

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

Filed: September 11, 2023

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| * * * * *           | * |                                   |
| WILLIE IVORY RANCE, | * | PUBLISHED                         |
|                     | * |                                   |
| Petitioner,         | * | No. 18-222V                       |
|                     | * |                                   |
| v.                  | * | Special Master Dorsey             |
|                     | * |                                   |
| SECRETARY OF HEALTH | * | Ruling on Entitlement; Influenza  |
| AND HUMAN SERVICES, | * | ("Flu") Vaccine; Shoulder Injury  |
|                     | * | Related to Vaccine Administration |
| Respondent.         | * | ("SIRVA").                        |
|                     | * |                                   |
| * * * * *           | * |                                   |

Leah VaSahnja Durant, Law Offices of Leah V. Durant, Washington, DC, for Petitioner.  
Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

### **RULING ON ENTITLEMENT**<sup>1</sup>

On February 13, 2018, Willie Ivory Rance ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).<sup>2</sup> Petitioner alleged that he suffered a left shoulder injury related to vaccine administration ("SIRVA") as the result of an influenza ("flu") vaccination administered on September 9, 2013. Petition at 1 (ECF No. 1). Respondent argued against compensation, asserting that Petitioner could not establish a SIRVA Table claim, and that any cause-in-fact claim was time-barred. Respondent's Report ("Resp. Rept.") at 6-7 (ECF No. 22).

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<sup>1</sup> Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc> in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that (1) Petitioner does not satisfy the SIRVA Table criteria, but (2) that the lookback provision of § 16(b) of the Vaccine Act applies, and thus, Petitioner's petition was timely filed, and (3) Petitioner has provided preponderant evidence that the flu vaccine caused his left shoulder injury, which satisfies his causation-in-fact burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

## **I. ISSUES TO BE DECIDED**

The nature of Petitioner's left shoulder injury, including diagnosis and causation, is in dispute. Joint Submission, filed Mar. 7, 2022, at 1-2 (ECF No. 67).

Petitioner argues he meets the criteria for a SIRVA Table claim. Petitioner's Motion for a Ruling on the Record ("Pet. Mot."), filed Mar. 7, 2022, at 6-11 (ECF No. 70). In the alternative, Petitioner asserts a causation-in-fact claim, and contends he has provided preponderant evidence that the flu vaccine caused his injury by satisfying all three Althen prongs. Id. at 11. He argues it is a timely non-Table claim under the lookback provision of § 16(b) of the Vaccine Act because the likelihood of success was significantly increased by the amendment adding SIRVA to the Vaccine Injury Table. Id. at 16-17.

Respondent argues Petitioner cannot establish a SIRVA Table claim and that a non-Table claim is barred by the Vaccine Act's statute of limitations. Resp. Response to Ruling on the Record ("Resp. Response"), filed Apr. 21, 2022, at 7-15 (ECF No. 71). Respondent contends the lookback provision does not apply because Petitioner was eligible to seek compensation prior to the Table change, and thus the change did not significantly increase his likelihood of receiving compensation based on the facts and circumstances of this case. Id. at 14-15. Respondent argues that even if the lookback provision applies, Petitioner is still not entitled to compensation because he has failed to provide evidence sufficient to satisfy the Althen criteria. Id. at 16-22.

Although both parties agree that Petitioner also has cervical radiculopathy,<sup>3</sup> Respondent argues that Petitioner's shoulder pain can be explained by his cervical radiculopathy (and other medical conditions) rather than by the flu vaccine. Resp. Response at 14, 19. However, Petitioner maintains that his previously asymptomatic radiculopathy does not explain his "dramatic" onset of shoulder symptoms. Pet. Mot. at 10-11. Instead, he argues the pain that radiated into the neck and beyond was a direct result of the shoulder injury that occurred "almost immediately after his vaccination." Id.

## **II. BACKGROUND**

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<sup>3</sup> Cervical radiculopathy is "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." Cervical Radiculopathy, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=101392> (last visited July 17, 2023).

### **A. SIRVA and the Vaccine Injury Table**

On March 21, 2017, the Secretary of Health and Human Services added SIRVA as an injury to the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B). Under the Vaccine Table Qualifications and Aids to Interpretation, SIRVA is defined as “shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm.” *Id.* at § 100.3(c)(10). “These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.” *Id.* Thus, SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.) and is not a neurological injury. *Id.* “[A]bnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).” *Id.*

A vaccine recipient shall only be considered to have suffered a SIRVA Table Injury if all of the following are met:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;<sup>[4]</sup>
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10)(i)-(iv).

### **B. Procedural History**

Petitioner filed his petition pro se on February 13, 2018, alleging that he sustained a left shoulder injury caused by a flu vaccine administered on September 9, 2013. Petition at 1. On February 21, 2018, Petitioner filed proof of vaccination and medical records from various facilities. Pet. Exhibits (“Exs.”) 1-8. An initial status conference was held on May 15, 2018, at which time Petitioner was informed that pursuant to the provisions of the Vaccine Act, he could hire an attorney. See Order dated May 15, 2018 (ECF No. 11). On June 29, 2018, a motion to substitute counsel for Leah Durant was filed. Consented Motion to Substitute Attorney Leah V. Durant in Place of Pro Se, filed June 29, 2019 (ECF No. 12). Upon request of Respondent, Petitioner filed additional medical records on February 7, 2019. Pet. Exs. 9-11.

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<sup>4</sup> A presumption of causation is afforded under the Vaccine Injury Table for SIRVA cases following flu vaccination if onset is equal to or less than 48 hours. 42 C.F.R. § 100.3(a)(XIV)(B).

On June 10, 2019, Respondent filed his Rule 4(c) Report and a concurrent motion to dismiss, in which he argued that contemporaneous medical records do not support a SIRVA Table claim and that Petitioner cannot alternatively allege a claim for actual causation because the lookback provision of § 16(b) of the Vaccine Act would not apply. Resp. Rept. at 6-7; Resp. Motion to Dismiss, filed June 10, 2019 (ECF No. 23). On February 19, 2020, the special master assigned to the case at the time denied Respondent's motion to dismiss on those grounds as premature and ordered Petitioner to file affidavits and corroborating evidence. Order Denying Motion to Dismiss dated Feb. 19, 2020, at 2 (ECF No. 26). Accordingly, on May 19, 2020, Petitioner filed his declaration<sup>5</sup> and a declaration of Flora Kennedy. Pet. Exs. 12-13. And on July 30, Petitioner filed supporting medical literature. Pet. Exs. 14-18.

The case was reassigned to the undersigned on July 31, 2020. Notice of Reassignment dated July 31, 2020 (ECF No. 35). On December 1, 2020, Petitioner filed an expert report from Dr. Uma Srikumaran. Pet. Ex. 19. On July 1, 2021, Respondent filed expert reports from Dr. Geoffrey D. Adams and Dr. Brian C. Callaghan. Resp. Exs. A, C.

On September 15, 2021, a Rule 5 conference was held. Rule 5 Order dated Sept. 16, 2021 (ECF No. 57). The undersigned encouraged the parties to resolve the matter informally. Id. at 4. In response to Petitioner's demand for settlement, Respondent indicated that he was not open to settlement negotiations and would continue to defend the case. Resp. Status Rept., filed Nov. 29, 2021 (ECF No. 60). On December 29, 2021, Petitioner filed a joint status report indicating that the parties had conferred and agreed to resolve the matter with a ruling on the record. Joint Status Rept., filed Dec. 29, 2021 (ECF No. 62).

Petitioner filed a motion for a ruling on the record and a supporting brief on March 7, 2022. Pet. Mot. Respondent filed his response on April 21, 2022, and Petitioner filed a reply on May 6, 2022. Resp. Response; Pet. Reply to Resp. Response ("Pet. Reply"), filed May 6, 2022 (ECF No. 72).

On October 28, 2022, the undersigned requested Petitioner to file a responsive expert report and additional medical records regarding diagnostic studies or a status report indicating the records do not exist. Order dated Oct. 28, 2022 (ECF No. 75). A status conference was held on December 13, 2022, to further discuss the additional information needed to adjudicate the case. See Order dated Dec. 14, 2022 (ECF No. 77). On January 27, 2023, Petitioner filed a status report indicating the requested records were unavailable for production. Pet. Status Rept., filed Jan. 27, 2023 (ECF No. 79). The status report detailed the steps Petitioner's counsel took to determine whether the specific diagnostic studies requested were performed, including retaining services to identify whether Petitioner's insurance paid for the studies. Id. The efforts however, failed to confirm the existence of the requested records. Id. Petitioner filed a supplemental expert report from Dr. Srikumaran on February 24, 2023. Pet. Ex. 36.

This matter is now ripe for adjudication.

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<sup>5</sup> This exhibit is titled "Affidavit" but it is not notarized, and therefore, the undersigned references it as a declaration.

## C. Factual History

### 1. Pre-Vaccination Medical History

Petitioner's pre-vaccination medical history includes chronic ischemic heart disease and coronary artery disease (bypass graft surgery in 2005 and circumflex artery stent in 2011), diabetes mellitus, congestive heart failure, lumbago, myalgia and myositis, hypertension, degeneration of lumbar or lumbosacral intervertebral disc disease (X-ray of spine in 2012), chronic pain syndrome, and chronic airway obstruction. Pet. Ex. 32 at 54-55.

Petitioner also has a history of chest pain radiating from his chest to his left arm and neck, however, the pain has never been attributed to prior vaccination or trauma. On November 29, 2010, Petitioner presented to the emergency department ("ED") complaining of "chest pain radiating to his left arm" since his colonoscopy two weeks prior. Pet. Ex. 9 at 1. He described "a substernal chest pressure rated 9 out of 10 in intensity, again with radiation to his left arm that ha[d] been intermittent in nature on exertion, and also while at rest." Id. The chest pain also "produced some associated shortness of breath." Id. On examination, his blood pressure was 151/96 and he had no joint pain, stiffness, swelling, or focal weakness. Id. at 1-2. An initial electrocardiogram ("EKG") showed "some T-wave inversions" but "no acute ST elevation." Id. at 2. A chest X-ray showed "prior sternotomy, no acute process." Id. There was "concern for ongoing [acute coronary syndrome]" and Petitioner was admitted to the chest pain unit for serial cardiac enzymes and a cardiology consultation. Id.

The next morning, Petitioner had a cardiology consultation with Dr. Rajib Choudhury. Pet. Ex. 9 at 62. Petitioner reported that following a colonoscopy a month earlier, he had "a lot of abdominal discomfort, which he attributed to the procedure" but yesterday, he "started developing pain in the left side of his neck radiating to his left arm." Id. Petitioner denied retrosternal discomfort and denied any recent trauma. Id. It was noted that Petitioner was hypertensive upon arrival to the ED the day before. Id. A follow-up EKG showed "normal sinus rhythm with left ventricular hypertrophy" and "nonspecific changes;" his cardiac enzymes were negative. Id. at 62-63. Past medical history noted coronary artery disease following his coronary artery bypass graft surgery in 2005. Id. at 62. "At that time, he had presented with chest pain. The chest pain was quite different from this current episode." Id. Dr. Choudhury's impression was hypertension and "[a]typical chest pain" with "no clinical signs of coronary ischemia." Id. at 63.

Similarly, on March 8, 2011, Petitioner presented to the ED complaining of pain in his chest radiating to his left upper extremity with shortness of breath, "reminiscent of the pain related to his previous heart attack." Pet. Ex. 9 at 58. Petitioner reported that earlier that morning he was doing chores around the house when he started to feel diaphoretic. Id. He described "pain and pressure in the chest that radiated to the left upper extremity and made him very short of breath. . . . [S]ince it started, it ha[d] been consistent if not[] getting a bit worse." Id. Petitioner denied any trauma. Id. Past medical history indicated that, in addition to the coronary artery bypass graft surgery in 2005, "he likely in 2009, had a coronary angiogram with stenting as well." Id. On examination, Petitioner's blood pressure was 207/122. Id. An EKG

showed marked ST elevations “suggestive of substantial inferior myocardial infarction.” Id. at 58-59. Cardiologist Dr. Michael Martin was contacted, and Petitioner’s diagnosis was ST elevation/acute myocardial infarction. Id. at 59.

## 2. Vaccination and Post-Vaccination Medical History

On September 9, 2013, Petitioner, at age 58, received a flu vaccine in his left deltoid at the office of his primary care provider (“PCP”), Dr. Harpeet Chhokar. Pet. Ex. 32 at 54-55.

Three days later, on September 12, 2013, Petitioner presented to the Valley Medical Center ED for “constant left sided chest pain which radiate[d] to left neck and down left arm.” Pet. Ex. 33 at 16. Petitioner reported “that he had a flu shot a couple days ago; since then [he] had left sided chest pain, up into left neck and down left arm; fe[lt] hard to breathe.” Id. at 7. Petitioner also had a left-sided headache and was concerned about a possible heart attack or stroke. Id. Upon presenting to the hospital, his pain score was a 10/10. Id. His pain decreased to a 9/10 after his first dose of nitroglycerin.<sup>6</sup> Id. at 8, 16. ED physician Dr. Russell L. Spies evaluated Petitioner the same day and noted Petitioner’s blood pressure was normal. Id. at 16, 19. He documented that Petitioner had “left chest pain radiating to the left side of his neck/head and left upper extremity for [three] days duration. . . . His chest pain and associated symptoms with abnormal EKG [were] concerning for acute coronary syndrome,” but he had “no focal neurologic deficits to suggest acute [cerebrovascular accident].” Id. at 19. Physical examination revealed “[g]ood range of motion in all major extremities” and “[n]o tenderness to palpitation or major deformities.” Id. at 17. Nursing notes later that day recorded, “[Petitioner] state[d] he [] had chest pain radiating to left arm and neck since having a flu shot on 9/[9], [and] [Petitioner] report[ed] at first he thought this pain was due to the flu shot but was concerned today when pain persisted.” Id. at 9. Dr. Spies recorded onset as September 9, 2013. Id. at 16.

Petitioner’s EKG showed “lateral T wave inversion” but “no acute ST segment elevation.” Pet. Ex. 33 at 18, 20, 22. His chest X-ray was normal, showing “prior median sternotomy” but “[n]o acute cardiopulmonary process.” Id. at 18, 22-23. Petitioner’s cardiac enzymes were negative. Id. at 20. After his third dose of nitroglycerin, Petitioner’s chest pain resolved but he still had “pain in the left side of his neck/head and left upper extremity” at a 6-7/10 in severity. Id. at 9, 19. He was admitted to the hospital for observation and a cardiology consultation was scheduled. Id. at 10, 20. Petitioner later complained of the nitroglycerin giving him a “headache occurring in the left side of his head and in his left face.” Id. at 12.

The next day, September 13, a cardiology evaluation was performed by Dr. Terence A. Block. Pet. Ex. 33 at 27. Dr. Block’s ultimate impression was “[l]eft arm pain, noncardiac.” Id. at 35. Dr. Block noted that Petitioner saw his PCP three days prior and Petitioner “believe[d] that he received either a flu shot or some sort of injection in his left arm. Subsequently, the left

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<sup>6</sup> Nitroglycerin “has antianginal, antihypertensive, and vasodilator properties and is used in medicine for the prophylaxis and treatment of angina pectoris, the treatment of congestive heart failure, as an adjunct in the treatment of myocardial infarction, and for blood pressure control or controlled hypotension during surgery.” Nitroglycerin, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=34091> (last visited July 18, 2023).



arm swelled, and he ha[d] had pain in the left arm constantly, with some radiation into the left side of his neck and a little bit into his chest.” Id. at 27. Dr. Block documented that while “[t]here ha[d] been fixation on chest discomfort,” Petitioner’s “pain and discomfort [were] mainly in his arm.” Id. Dr. Block noted Petitioner’s past cardiac history but found the current EKG and chest X-ray to be “unremarkable” with “no acute abnormalities.” Id. at 27-28. His cardiac biomarkers were also normal. Id. at 28. “The left arm [was] nontender.” Id. Dr. Block concluded, “[t]here is no reason to even remotely suspect that this is cardiac in nature.” Id. Instead, the impression was “[l]eft arm pain” and questioned whether it was “related to reaction to recent intramuscular injection.” Id. No further cardiac evaluation was recommended at that time. Id.

The same day, September 13, 2013, Petitioner was evaluated by Dr. Arthur F. Sullivan who documented that Petitioner presented to the ED with “pain in [] left side of his chest with radiation to his neck and arm.” Pet. Ex. 33 at 20. Petitioner had three sets of negative cardiac enzymes and was evaluated and cleared by cardiology. Id. at 24. Dr. Sullivan also noted that Petitioner’s EKG showed “Q waves consistent with previous inferior [myocardial infarction] but no acute changes.” Id. Dr. Sullivan wrote that Petitioner had “an injection in his left arm for a flu shot 2-3 days ago which may be the etiology of his pain.” Id. Petitioner was discharged from the hospital that day. Id. at 20.

On October 9, 2013, Petitioner saw Dr. Chhokar for a follow-up visit for his “multiple chronic medical problems,” specifically, chronic low back pain. Pet. Ex. 32 at 53. At this visit there were no documented complaints of shoulder or arm pain, no chest pain, and no shortness of breath. Id. A physical examination showed mild decreased range of motion of the lumbar sacral spine as well as “muscle tenderness” but did not specify where. Id. Dr. Chhokar referred Petitioner to physical therapy and discussed a referral to a pain specialist. Id. at 54. Later that month, on October 28, Petitioner presented to Apple Physical Therapy for an initial lumbar/sacral physical therapy evaluation. Pet. Ex. 30 at 62. The presenting conditions were chronic low back pain, chest pain, low back cramping, difficulty walking, and shortness of breath. Id. In a patient worksheet Petitioner completed, he indicated he currently had muscle weakness but did not specify where. Id. at 64. He also indicated he could not “carry heavy loads overhead” or “reach up to a lower shelf without increased symptoms.” Id. at 65. At a follow-up visit with Dr. Chhokar on November 8, 2013, Petitioner reported his “chronic pain low back and muscles improved by attending physical therapy twice a week.” Pet. Ex. 32 at 51. Dr. Chhokar instructed Petitioner to continue physical therapy. Id. at 52.

On November 25, 2013, Petitioner presented to the Valley Medical Center ED with complaints of “left upper extremity pain.” Pet. Ex. 33 at 79. Petitioner told the triage nurse that “starting yesterday, [he] developed left sided neck pain that radiate[d] down [his] left shoulder to [his] arm and left chest.” Id. at 76. Petitioner reported that “[t]he pain started back in September after intramuscular injection.” Id. at 79. He explained the pain was constant but that it was “worse in the morning” and “with movement and touch.” Id. There was no associated numbness or weakness. Id. Dr. Todd Davis’ physical examination revealed Petitioner was “[t]ender in the left lateral neck and general shoulder region” but that there was no swelling of the upper extremities. Id. at 81-82. Petitioner’s “[p]ain increase[d] with range of motion of left shoulder.” Id. at 81. An EKG and chest X-ray performed that day were normal. Id. at 83. Dr. Davis’

impression included “[l]eft upper extremity muscular pain” and cervical muscular pain. Id. at 84.

Petitioner returned to his PCP on December 6, 2013 for a follow-up on his chronic low back pain, and he indicated that he was seen in the ED two weeks prior for “muscle strain neck and right shoulder” with “no acute radicular [symptoms].” Pet. Ex. 32 at 50. There was no mention in this visit’s notes of Petitioner’s left shoulder pain. Id. Cervicalgia was listed as an acute problem in the notes. Id. at 51. Dr. Chhokar discussed with Petitioner considering physical therapy next month for his neck pain since he completed physical therapy for his low back pain. Id.

Dr. Anthony Rains of Molina Healthcare evaluated Petitioner on December 30, 2013. Pet. Ex. 32 at 114-28. Petitioner’s flu shot from November<sup>7</sup> 2013 was recorded and Petitioner’s pain at the time of Dr. Rains’ evaluation was “very severe.” Id. at 116. In the health assessment/evaluation form Dr. Rains completed for Petitioner, it was noted that Petitioner had “L[eft] neck, shoulder, and upper arm pain since [flu] shot L[eft] shoulder [November 2013], seen in [ED] November 25, 2013 and [diagnosed] w[ith] cervical strain and [left] shoulder sprain.” Id. at 125, 127. Petitioner was to get magnetic resonance imaging (“MRI”) soon. Id.<sup>8</sup>

Petitioner returned to Dr. Chhokar on January 6, 2014, complaining of “left shoulder pain” but reporting that his “neck pain resolved.” Pet. Ex. 32 at 48. “Bursae and tendon in shoulder region” was listed as an acute problem. Id. at 49. Examination showed “mild dec[reased] [range of motion] [lumbar sacral] spine, muscle tenderness, mild dec[reased] [range of motion] left shoulder, neck.” Id. X-rays were ordered and Dr. Chhokar referred Petitioner to physical therapy for his left shoulder. Id.

A left shoulder X-ray performed on January 10, 2014 showed the shoulder was “within normal limits.” Pet. Ex. 30 at 56. A cervical spine X-ray performed the same day showed “[d]egenerative disc disease of C4-C5,” “[s]traightening consistent with spasm,” and “[m]inor retrolisthesis<sup>9</sup> of C4 which most likely due to underlying degenerative disease.” Id. at 55.

The referral for physical therapy dated January 6, 2014 listed diagnoses of left shoulder pain and rotator cuff syndrome as well as “left shoulder tendonitis, rotator cuff pain, [and] neck pain.” Pet. Ex. 30 at 16-19. No cervical issue was noted. Id. On January 13, 2014, Petitioner saw Megan Richard, Doctor of Physical Therapy (“DPT”), at Apple Physical Therapy for an

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<sup>7</sup> These records incorrectly indicate Petitioner’s flu shot was in November 2013. Petitioner’s flu shot was September 9, 2013. Pet. Ex. 32 at 54-55.

<sup>8</sup> Petitioner filed a status report on January 27, 2023, indicating the steps Petitioner’s counsel took to determine whether any left shoulder MRIs were performed. Pet. Status Rept. at 1-2. The efforts failed to show that any shoulder MRI results were available for production. Id.

<sup>9</sup> Retrolisthesis is the “posterior displacement of one vertebral body on the subjacent body.” Retrospondylolisthesis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=43594> (last visited Aug. 3, 2023).



initial evaluation of his left shoulder. Id. at 50-51. The evaluation notes indicated Petitioner started noticing left shoulder pain three to four months earlier. Id. Petitioner reported tingling down his arm; headaches; and explained he had difficulty sleeping, lifting with his left arm, dressing himself, and performing general activities of daily living. Id. Although he had normal range of motion, he had pain with range of motion, and tested positive for impingement tests including Neer, Hawkins, and empty can. Id. at 51. Physical therapy was recommended for two sessions a week for five weeks. Id.

Physical therapy notes from February 3, 2014 indicated Petitioner had “total arm soreness” and reported “dropping a pitcher of tea due to p[ain].” Pet. Ex. 30 at 46. Petitioner again reported “dropping things” at a visit on February 5. Id.

On February 6, 2014, Petitioner presented to Dr. Chhokar for a follow-up complaining of “neck pain radiating to left arm” and intermittent paresthesias<sup>10</sup> in his hand. Pet. Ex. 32 at 46. The cervical spine X-ray showed degenerative disc disease at C4-5. Id. “Brachial neuritis or radiculitis” and “degeneration of cervical intervertebral disc” were noted as acute problems. Id. at 47.

At a follow-up visit on March 6, 2014, Petitioner reported neck pain of 9/10 that “radiat[ed] to left arm” and difficulty sleeping. Pet. Ex. 32 at 105. Dr. Chhokar prescribed acetaminophen-oxycodone and referred Petitioner for NCS/EMG,<sup>11</sup> “then orthopedics spine specialist to consider MRI/spinal injection if indicated.” Id. at 106. On March 20, he was referred to the Swedish Orthopedic Institute with a diagnosis of “cervical spine degenerative disc disease C4-5[,] C5 cervical radiculitis, [and] left arm/shoulder pain.” Id. at 104.

On March 26, 2014, Dr. Justin L. Esterberg, of Orthopedic Physician Associates (“OPA”), examined Petitioner for complaints of “severe left upper extremity pain, numbness and paresthesias since October.” Pet. Ex. 32 at 129. His notes indicated that Petitioner’s pain extended “from the left side of his neck, through the left shoulder, lateral arm, dorsal forearm, and into the dorsal hand” and “[was] worse with most positions.” Id. Dr. Esterberg noted that Petitioner’s symptoms “started acutely” and caused “pain ever since” but that Petitioner “ha[d] not had this type of problem before.” Id. Since then, there had “been some episodes of flares of pain enough to go to the [ED] on a couple of occasions.” Id. Dr. Esterberg noted that “[Petitioner] did have a flu shot around the same time that it started and attribute[d] that to the ongoing pain.” Id. On physical examination, Petitioner had full extension range of motion but “[m]ild distress in certain positions due to pain,” normal neck alignment “although he [held] in a slightly flexed position,” increased pain with neck extension, and slightly diminished sensation

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<sup>10</sup> Paresthesia refers to “an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus.” Paresthesia, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=37052> (last visited July 21, 2023).

<sup>11</sup> Petitioner filed a status report on January 27, 2023, indicating the steps Petitioner’s counsel took to determine whether any NCS/EMG testing was performed. Pet. Status Rept. at 1-2. The efforts failed to show that any EMG testing results were available for production. Id.

over the dorsal left hand. Id. at 130. Spurling<sup>12</sup> was positive, and Hoffmann and clonus were negative. Id. Dr. Esterberg's impression was "cervical radiculitis, cervical radiculopathy, left side, likely C7." Id. A cervical MRI was ordered. Id.

At a physical therapy appointment on April 23, 2014, Petitioner reported his left arm pain level was a 10/10. Pet. Ex. 30 at 5. Physical therapist Jeff Mitsch evaluated Petitioner and noted Petitioner had limited grip strength in his left hand and was "[u]nable to lift and pour a jug of milk." Id. Petitioner was discharged from physical therapy on May 28, 2014. Id. at 4. On the day of discharge, Petitioner's pain was a 7/10. Id. Discharge notes indicated Petitioner still described "radicular type [symptoms] through the l[eft] [upper extremity]." Id.

Petitioner returned to OPA on July 23, 2014, with a chief complaint of "[l]eft upper extremity pain." Pet. Ex. 32 at 133. He reported no change in his pain since his last visit but was taking gabapentin for the pain which seemed to help. Id. At this visit, Dr. Esterberg reviewed Petitioner's MRI that was performed on June 25, and explained it showed degenerative changes at C3-4 and C4-5. Id. Dr. Esterberg opined Petitioner had "C4-5 stenosis<sup>13</sup> which may be causing a cervical radiculitis, but the distribution [was] throughout the left upper extremity." Id. He noted it was "nondermatomal." Id.

Dr. Chhokar recorded Petitioner's "chronic neck pain with radiculitis left arm" at a follow-up visit on August 7, 2014. Pet. Ex. 32 at 35. Petitioner was instructed to return if symptoms worsened. Id. at 36.

On June 5, 2015, Petitioner present to Valley Medical Center ED for the "[o]nset of sudden left side [chest pain] 45 min[utes] ago radiating into [his] left arm." Pet. Ex. 33 at 133. Petitioner had low hemoglobin. Id. at 143. The diagnosis was "chest pain" and Petitioner was discharged. Id. at 144.

On February 11, 2016, Petitioner presented to Auburn Medical Center ED with "mid-chest sharp pain going to [his] left arm." Pet. Ex. 29 at 28. He also had shortness of breath. Id. There were no irregular imaging findings. Id. at 33. Diagnoses were chest pain and anemia. Id. at 34. Two weeks later, on February 26, 2016, Petitioner presented to an ED again with chest pain "radiating down his left arm, jaw[,] and neck." Pet. Ex. 33 at 198. Petitioner denied painful joints but endorsed numbness in his left hand. Id. He also was "slightly hypertensive" upon presentation and had "moderate anemia." Id. at 202-03. The diagnosis was "unspecified chest pain." Id. at 203.

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<sup>12</sup> In a spurling test "(for cervical radiculopathy)[,] the examiner presses down on the top of the head while the patient rotates the head laterally and into hyperextension; pain radiating into the upper limb ipsilateral to a rotation position of the head indicates radiculopathy." Spurling Test, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=112983> (last visited July 31, 2023).

<sup>13</sup> A stenosis is "an abnormal narrowing of a duct or canal." Stenosis, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=47090> (last visited July 21, 2023).

As a result of Petitioner's progressive weakness and sensory loss, as well as usage of physical therapy and neuropathic medications, another MRI of the cervical spine was conducted on December 14, 2016 that revealed disc bulges at C3-4 and C4-5. Pet. Ex. 6 at 1-2.

No other relevant medical records were submitted.

## **D. Declarations**

### **1. Petitioner's Declaration**

In his declaration, Petitioner indicated he received the flu shot in his left arm on September 9, 2013. Pet. Ex. 12 at ¶ 2. The vaccine was administered by Dr. Chhokar, who was his doctor at the time. Id. He remembered the "shot hurt so bad and the pain was immediate. [He] even jumped when the needle went in." Id. He recalled it hurt so much that he had to take pain medication when he got home but that even then, "the pain didn't go away." Id.

Three days later, he went to the ED because the "throbbing in his left arm was so strong [he] thought he was having a heart attack." Pet. Ex. 12 at ¶ 3. He was informed his heart was okay, but that the pain in his shoulder could be from the recent flu shot. Id. "[He] was shocked a vaccine could hurt that much," and despite his hopes, the pain did not go away on its own. Id.

He went back to Dr. Chhokar in October 2013 and discussed his arm. Pet. Ex. 12 at ¶ 4. Petitioner recounted, "[i]n fact, every time [he would] go to see him [he would] tell him about [his] arm, even if [he] was there for other reasons." Id. He told Dr. Chhokar he "needed medication or something that could help stop the pain." Id.

At the time, Petitioner was living with his friend Flora Kennedy and had been since 2007. Pet. Ex. 12 at ¶ 5. He told Mrs. Kennedy his "arm still hurt from getting a flu shot" and she recommended he look for another doctor. Id. He went to many appointments because of his left arm pain. Id. at ¶ 6. In November 2013, he went to the ED, and in December and January, he went back to Dr. Chhokar. Id. From January through May 2014, he went to physical therapy and reported how his "arm felt weak," that he was "dropping things," and had "problems lifting things with [his] left arm." Id.

Around this time, Petitioner worked as a cook preparing foods for sporting events. Pet. Ex. 12 at ¶ 7. However, he was in a lot of pain while trying to work because his "shoulder still hurt from the shot." Id. He remembered "struggling to hold heavy pots and pans" and being nervous that he might spill hot food because his "left arm was so weak." Id. He required the use of two hands for anything heavy "which made it hard to cook fast during the busy events." Id.

As of May 14, 2020, the date Petitioner executed his declaration, his "arm still [shook] from time to time" and he had to "lean on it or hold it with [his] right hand to keep it from shaking and from the pain. [He] [was] still tak[ing] gabapentin for the pain which help[ed] some." Pet. Ex. 12 at ¶ 9. He tried to exercise his "left arm by squeezing a tennis ball, but [] [could not] do much else." Id.

## 2. Declaration of Flora Kennedy

In her declaration, Flora Kennedy explains she is a close friend of Petitioner and has known him for over 13 years. Pet. Ex. 13 at ¶ 1. Petitioner lived with Mrs. Kennedy and her husband from 2007 to 2020. Id.

Mrs. Kennedy took Petitioner to get his flu shot on September 9, 2013. Pet. Ex. 13 at ¶ 2. She waited for him in the waiting room and remembered when Petitioner came out afterwards because he said “Dr. Chhokar must have given him an extra dose because his shoulder was really sore and was bothering him.” Id. It continued to bother Petitioner for the next few days and “[h]e ended up going to the [ED] because his left arm was throbbing so much.” Id.

She recalled Petitioner’s pain continued in the subsequent weeks. Pet. Ex. 13 at ¶ 3. Petitioner “point[ed] to the back of his left shoulder” and told Mrs. Kennedy that “the doctor gave him the shot in the wrong place.” Id. She advised him to see another doctor. Id.

While Petitioner lived with the Kennedys, Petitioner would come home and tell her “how much pain he was in at work and how he kept dropping dishes.” Pet. Ex. 13 at ¶ 4. She also remembered “he would always spill coffee at home because his arm would shake while holding the mug.” Id.

As of May 14, 2020, the date Mrs. Kennedy executed her declaration, she stated “[Petitioner] still complain[ed] about weakness and constant soreness in his left arm.” Pet. Ex. 13 at ¶ 4.

## E. Expert Reports

### 1. Petitioner’s Expert, Dr. Uma Srikumaran<sup>14</sup>

#### a. Background and Qualifications

Dr. Srikumaran is a board-certified orthopaedic surgeon. Pet. Ex. 19 at 1. He earned his M.D. from the Johns Hopkins University School of Medicine, where he also completed his residency in orthopaedic surgery, and trained as a shoulder specialist while he was a fellow at Harvard. Id. He is an attending physician, Director of the Shoulder Fellowship, and Chair of Orthopaedic Surgery at the Howard County General Hospital. Id.; Pet. Ex. 20 at 1. Dr. Srikumaran’s clinical focus is on disorders involving the shoulder. Pet. Ex. 20 at 9. Each year, he sees approximately 2500-3000 patients for shoulder issues and performs around 400-500 shoulder surgeries. Pet. Ex. 19 at 1. Within the past five years, he has treated approximately 10-12 patients with shoulder dysfunction following vaccination. Id. Dr. Srikumaran is also an Associate Professor of Orthopaedic Surgery in the Shoulder Division at the Johns Hopkins School of Medicine. Id. He is a peer reviewer for several orthopaedic journals and has published numerous articles regarding shoulder surgery. Id.

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<sup>14</sup> Petitioner submitted two expert reports authored by Dr. Srikumaran. Pet. Exs. 19, 36.

## b. Opinion

Dr. Srikumaran opined with a “reasonable degree of medical certainty,”<sup>15</sup> that Petitioner suffered an injury consistent with a SIRVA Table claim and further believed Petitioner has a causation-in-fact claim. Pet. Ex. 19 at 2.

### i. Table Injury Claim

Dr. Srikumaran believed the preponderance of evidence supports the four elements required to demonstrate a SIRVA Table injury. Pet. Ex. 19 at 12. He acknowledged Petitioner also had evidence consistent with cervical radiculopathy but reasoned “that diagnosis alone cannot explain all [of] [P]etitioner’s shoulder symptoms and signs that resulted immediately after vaccination.” Id. He further opined that “the shoulder condition most likely was the cause of the cervical condition becoming symptomatic.” Id. Dr. Srikumaran stated the contemporaneous medical records and sworn statements of Petitioner and Flora Kennedy “strongly suggest [Petitioner’s] left shoulder condition was caused by the September 9, 2013[] vaccination, supporting the SIRVA claim as a [T]able injury.” Id. at 6.

First, Dr. Srikumaran believed there is no documented history of any prior issues or medical care specifically relating to Petitioner’s left shoulder, thus satisfying the first element of a SIRVA Table claim. Pet. Ex. 19 at 7. He highlighted that Respondent’s Rule 4(c) Report also acknowledged that the first criterion is satisfied. Id. (citing Resp. Rept. at 6 (providing that Petitioner fails to satisfy the requirements of a Table SIRVA claim because he cannot satisfy the second, third, and fourth elements)). Respondent’s expert, Dr. Abrams, opined to the contrary, that Petitioner did have a history left upper extremity pain prior to the September 2013 flu vaccination. Pet. Ex. 36 at 1; Resp. Ex. A at 11. In response, Dr. Srikumaran opined that while the presenting complaints of the ED visits used to support Dr. Abrams’ claim are similar, the “cause of them [was] found to be different” each time. Pet. Ex. 36 at 1.

For example, in February 2011, Petitioner presented to the ED with chest pain and was diagnosed with costochondritis.<sup>16</sup> Pet. Ex. 36 at 1 (citing Pet. Ex. 9 at 56-57). And on other occasions, the workups were related to “atypical chest pain.” Id. at 1-2; see, e.g., Pet. Ex. 9 at 58-59, 62-63; Pet. Ex. 33 at 143-44; Pet. Ex. 29 at 33-34. Dr. Srikumaran compared those visits to the one on September 12, 2013, three days after receiving the flu vaccine. Pet. Ex. 36 at 1. While Petitioner initially complained that day of “chest pain with radiation into the arm and neck, the workup rule[d] out a cardiac origin and instead [was] determined to be of musculoskeletal cause.” Id. According to Dr. Srikumaran, this is demonstrated by cardiologist

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<sup>15</sup> Although Dr. Srikumaran used the standard of reasonable degree of medical certainty in some places in his report, the standard applicable to Vaccine Act cases is preponderant evidence, a lesser standard. § 13(a)(1).

<sup>16</sup> Costochondritis is “inflammation of the cartilaginous junction between a rib or ribs and the sternum.” Costochondritis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=11357> (last visited July 26, 2023).



Dr. Block who contemporaneously documented “there has been a fixation on chest pain, although his pain and discomfort are mainly in his arm,” “there [was] no reason to even remotely suspect this is cardiac in nature,” and questioned whether Petitioner’s left arm pain was “related to reaction to recent intramuscular injection.” Id. (quoting Pet. Ex. 9 at 16). Similarly, when Petitioner presented to the ED on November 25, 2013, Petitioner reported “that his symptoms started after receiving the [flu] vaccine.” Id.; see Pet. Ex. 33 at 79. The diagnosis then was “left upper extremity muscular pain and cervical muscular pain.” Pet. Ex. 33 at 84; see Pet. Ex. 36 at 1.

Petitioner’s “ongoing chest pain” was not ignored by Dr. Srikumaran; in fact, he believed that condition was supported by Petitioner’s 2021-2022 cardiac workup. Pet. Ex. 36 at 2 (citing Pet. Ex. 35 at 22-46). But Dr. Srikumaran emphasized the difference between the numerous ED visits, explaining that

[i]t is important to consider that although the symptoms of chest pain (classically described as left sided chest pain with radiation into the left arm) can be similar to musculoskeletal pain, [] the workup in the [ED] on the dates closely following the vaccination yields the diagnosis of musculoskeletal shoulder and neck pain, whereas the other visits all determine the etiology to be related to pre-existing cardiac disease and related atypical chest pain.

Id. He concluded, “[P]etitioner should not be determined ineligible of a [T]able injury because of a pre-existing, and arguably worsening, cardiac condition that can mimic musculoskeletal pain.” Id.

Next, he opined Petitioner’s pain occurred within the specified timeframe of 48 hours based on complaints to medical providers. Pet. Ex. 19 at 7. Dr. Srikumaran explained that Petitioner “consistently and reliably report[ed] immediate shoulder pain after vaccination to his varied medical providers.” Id. At his initial visit to the ED, records document that “[Petitioner] state[d] that he had a flu shot a couple days ago; since then [he] had left sided chest pain, up into neck and down left arm; fe[lt] hard to breathe.” Id. (quoting Pet. Ex. 33 at 7). Petitioner continued to report the onset of his pain in relation to vaccination at later appointments. Id. For example, Dr. Esterberg noted “[h]e did have a flu shot around the same time that it started and attribute[d] that to the ongoing pain.” Id. (quoting Pet. Ex. 32 at 129). Accordingly, Dr. Srikumaran opined that Petitioner’s pain “begin immediately after the injection and worsened after [] time,” thus satisfying the second criterion of a SIRVA Table claim. Id. at 8.

With regard to the third criterion (pain limited to the shoulder), Dr. Srikumaran disagreed with Respondent’s Rule 4(c) Report that “radiation of pain down the arm or to the neck is inconsistent with [a] SIRVA” Table claim. Pet. Ex. 19 at 8 (citing Resp. Rept. at 6). Instead, he opined “[r]adiation is simply one way to characterize the pain and is common in various directions for common shoulder related diagnoses such as bursitis or capsulitis.” Id.

Because there are layers of muscles, ligaments, and tendons that bridge the areas among the shoulder region and cervical spine, Dr. Srikumaran stated “it is easy to understand that an injury affecting one area of the shoulder . . . can cause compensatory overuse of surrounding

musculature, particularly [] leading into the neck.” Pet. Ex. 36 at 4. And “inflammation of these areas can cause compression on nerves to cause radicular symptoms.” Id. “This, in turn, can result in neck pain, causing a previously asymptomatic neck condition (disc degeneration/arthritis) to become symptomatic.” Id.; see also Pet Ex. 19 at 9.

He offered literature to note that “symptoms and presentations do not always neatly fit into one or another category (neck vs. shoulder).” Pet. Ex. 36 at 3. Gorski and Schwartz<sup>17</sup> defined “referred shoulder impingement syndrome” to describe the combination of cervical pain and positive proactive shoulder tests results. Pet. Ex. 17 at 1. “The proposed mechanism explaining this connection is muscular spasm or dysfunction of the numerous muscles that connect the shoulder and neck.” Pet. Ex. 19 at 9 (citing Pet. Ex. 17 at 3).

Dr. Srikumaran noted that he has seen this in his own practice as well; many patients present with findings consistent with both shoulder and cervical issues. Pet. Ex. 19 at 9. He explained “it is typical for patients with shoulder pain to attempt to mitigate their pain by adjusting their shoulder girdle (shoulder blade)” with other surrounding muscles, “which may lead to spasms and alter their neck position and mechanics.” Id. He noted this also occurs with the lower body; “[p]atients with knee pain often develop hip and/or ankle pain from compensating with different muscle groups.” Pet. Ex. 36 at 4.

Relatedly, Dr. Srikumaran believed Petitioner satisfies the fourth criterion of a SIRVA Table claim—that no other condition or abnormality explains Petitioner’s symptoms. Pet. Ex. 19 at 10. He disagreed with Respondent’s Rule 4(c) Report that cervical radiculopathy explains all of Petitioner’s symptoms and opined, “cervical radiculopathy does not explain [Petitioner’s] shoulder symptoms [] [or] positive impingement signs (objective physical exam findings supporting a shoulder origin and argues against a cervical origin), [but] the cervical radiculopathy could explain [Petitioner’s] neck pain and radiation of pain beyond the shoulder.” Id.

He opined “[i]t is not unusual to have chronic degenerative conditions of both the shoulder and the neck, as by definition, both are age related. In fact, many patients present with historical details, physical exam findings, diagnostic tests, and imaging results that can support both diagnoses.” Pet. Ex. 19 at 8. Thus, to further explain why Petitioner described symptoms beyond the shoulder and to support his argument for the fourth Table criterion, Dr. Srikumaran summarized the general characteristics of shoulder pathology and cervical pathology and indicated they can often overlap. Id. at 8-9.

For example, “pain with arm/shoulder abduction (moving away from body and up, similar to impingement signs),” “anterior shoulder pain with radiation distally into the biceps muscle,” nighttime and sleep disturbances, and positive provocative tests are consistent with shoulder pathology. Pet. Ex. 19 at 8. Relief of pain with arm/shoulder abduction, pain in the lateral portion of the shoulder girdle, “burning or electric pain . . . in the neck and radiating

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<sup>17</sup> Jerrold M. Gorski & Lawrence H. Schwartz, Shoulder Impingement Presenting as Neck Pain, 85 J. Bone & Joint Surgery 635 (2003). This is also cited by Respondent’s expert, Dr. Abrams. Resp. Ex. A, Tab 3.

through the shoulder and distally beyond the elbow,” and positive provocative shoulder tests are consistent with cervical or neurologic pathology. Id. at 9. In summation, both conditions can present with positive provocative tests, but a distinguishing characteristic is whether the pain is relieved or exacerbated with arm/shoulder abduction. See id. at 8-9. Additionally, “[p]atients with symptoms from the cervical spine typically do not have point tenderness over the shoulder in contrast to those patients with primary shoulder disease.” Pet. Ex. 27 at 3.<sup>18</sup>

He cited Bokshan et al.,<sup>19</sup> which found “that approximately 1 in 10 patients referred for cervical radiculopathy have comorbid shoulder pathology. In addition, pain reported in the neck may represent referred pain from the shoulder girdle and vice versa.” Pet. Ex. 21 at 1. But in most cases when patients present with both positive shoulder and cervical provocative tests, Dr. Srikumaran summarized that “treatment of the shoulder first resolved the pain in the neck.” Pet. Ex. 19 at 9-10 (citing Pet. Ex. 23 at 1, 4-5;<sup>20</sup> Pet. Ex. 27 at 7-8).

Here, Dr. Srikumaran found “substantial evidence consistent with shoulder pathology” and “some evidence of cervical radiculopathy,” and both were entertained by treating physicians. Pet. Ex. 19 at 10; Pet. Ex. 36 at 3. Petitioner had “muscle tenderness[] [and] mild dec[reased] [range of motion] [in his] left shoulder” and difficulty sleeping. Pet. Ex. 19 at 10 (quoting Pet. Ex. 32 at 49). Petitioner reported having pain in his neck and shoulder and a physical examination showed “[p]ain increase[d] with range of motion of left shoulder.” Id. (quoting Pet. Ex. 33 at 81). Dr. Srikumaran explained that a shoulder elevation test “would be expected to relieve pain in an individual with a cervical pathology.” Id. Dr. Srikumaran initially noted that a “cervical MRI was ordered but did not find objective evidence of a clear or acute injury that could explain [Petitioner’s] symptoms.” Id. He later clarified that a cervical spine MRI and X-ray “show[ed] pathology consistent with degenerative cervical spine disease,” but that “these were previously asymptomatic conditions.” Pet. Ex. 36 at 3.

But the cervical radiculopathy symptoms, radiation of pain beyond the shoulder into the hand for example, “[were] not directly from the vaccination. [Dr. Srikumaran] believe[d] the vaccination triggered and exacerbated a pre-existing cervical degenerative condition.” Pet. Ex. 19 at 10. In other words, he agreed that Petitioner also had symptoms consistent with cervical radiculopathy but opined those symptoms came after the initial shoulder pain. See id. “[T]he time course suggest[ed] [Petitioner] started to experience shoulder and arm pain first, and this later led to cervical pain, neither of which he had any evidence of prior to vaccination.” Id.; see also Pet. Ex. 36 at 3.

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<sup>18</sup> Stephen G. Manifold & Peter D. McCann, Cervical Radiculitis and Shoulder Disorders, 368 *Clinical Orthopaedics & Related Rsch.* 105 (1999).

<sup>19</sup> Steven L. Bokshan et al., An Evidence-Based Approach to Differentiating the Cause of Shoulder and Cervical Spine Pain, 129 *Am. J. Med.* 913 (2016).

<sup>20</sup> Richard J. Hawkins et al., Cervical Spine and Shoulder Pain, 258 *Clinical Orthopaedics & Related Rsch.* 142 (1990).

Dr. Srikumaran concluded, “it is not simply the presence of another condition (cervical radiculopathy) that invalidates a SIRVA claim, but rather that the other condition can explain the patient’s constellation of symptoms.” Pet. Ex. 19 at 10. “The consistent and reliable subjective reporting in this case is then further supported by objective physical exam findings as well as objective diagnostic tests making a strong case for the vaccination as the cause of the shoulder pain. This, in turn, . . . led to the cervical radiculopathy becoming symptomatic.” Id. at 11.

## ii. Causation-In-Fact Claim

In addition to the Table criteria, Dr. Srikumaran opined the criteria for a causation-in-fact claim are also met. Pet. Ex. 19 at 2. He opined “[t]he general, and specific theory in this case, of causation of shoulder dysfunction related to vaccination is the initiation of inflammation directly related to vaccine antigen being delivered to or near the bursa or synovium of the joint.” Id. at 11-12 (emphasis omitted); see also Pet. Ex. 36 at 4.

### 1. Althen Prong One

For support that the flu vaccine can cause a SIRVA, Dr. Srikumaran cited Atanasoff et al.<sup>21</sup> Pet. Ex. 19 at 12 (citing Pet. Ex. 14). In Atanasoff et al., the authors identified thirteen cases filed in the database of claims submitted to the Vaccine Program between 2006 to 2010 where “vaccine administration led to significant shoulder pain and dysfunction.” Pet. Ex. 14 at 1-2. Based on their investigation, the authors’ proposed mechanism was “the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction.” Id. at 1. “[T]he rapid onset of pain with limited range of motion following vaccination . . . [was] consistent with a robust and prolonged immune response.” Id. at 3. The authors noted that some of their MRI findings “may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation. Other findings such as fluid collections, localized tendon inflammation, and bursitis [were] more consistent with the vaccine needle over-penetration mechanism.” Id. at 3-4. According to Dr. Srikumaran, many of the cases studied “recall[ed] a mechanism that could support injection of antigenic material into the bursa (high deltoid).” Pet. Ex. 19 at 15.

Dr. Srikumaran also cited Bodor and Montalvo<sup>22</sup> for support of the proposed mechanism and the association with the vaccine administration technique. Pet. Ex. 19 at 14 (citing Pet. Ex. 16). In Bodor and Montalvo, the authors examined two patients with shoulder pain and weakness following vaccination. Pet. Ex. 16 at 1-2. Both cases “involved injections ‘high’ (within 1-2 cm of the acromial bone) into the deltoid muscle with symptoms beginning two days after injection.” Pet. Ex. 19 at 14; see Pet. Ex. 16 at 1-2. The authors hypothesized that the “vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response.” Pet. Ex. 16 at 1-2. They explained that “[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and

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<sup>21</sup> S. Atanasoff et al., Shoulder Injury Related to Vaccine Administration (SIRVA), 28 Vaccine 8049 (2010).

<sup>22</sup> Marko Bodor & Enoch Montalvo, Vaccination-Related Shoulder Dysfunction, 25 Vaccine 585 (2007).

inflammation of the shoulder capsule,” as well as “adhesive capsulitis.” Id. at 2. Because multiple structures within the shoulder were involved in both patients, Bodor and Montalvo found this suggested “a primary inflammatory etiology rather than a mechanical overuse problem.” Id. at 3. The authors concluded that “the diagnosis of vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection.” Id.

A report by Arias et al.<sup>23</sup> also supplemented Dr. Srikumaran’s proposed theory and “provide[d] the best evidence as to a feasible time frame for the development of SIRVA.” Pet. Ex. 19 at 16 (citing Pet. Ex. 15). Arias et al. systematically reviewed literature and the Spanish Pharmacovigilance System database (FEDRA) finding a total of 45 cases (including the 15 reported by Atanasoff et al. and Bodor and Montalvo) with a majority reporting pain within 48 hours but ranging from a few hours to two months. Pet. Ex. 15 at 2. The most common diagnosis was bursitis and tendonitis. Id. at 6. Dr. Srikumaran noted the authors also reported a great number of cases reporting a high injection location. Pet. Ex. 19 at 16 (citing Pet. Ex. 15 at 5). Dr. Srikumaran explained that these authors, like Atanasoff et al. and Bodor and Montalvo, “surmise the cause to be an immune mediated response of inflammation related to antigens or adjuvants injected into the bursal tissue, likely from poor technique related to various factors (site, needle choice, angle and location of injection, not accounting for patient size variation).” Id. (citing Pet. Ex. 15 at 1).

Finally, Dr. Srikumaran cited Hesse et al.<sup>24</sup> for epidemiologic evidence supporting the association of subdeltoid bursitis after flu vaccination. Pet. Ex. 19 at 11 (citing Pet. Ex. 25). Research found “an increased risk of subdeltoid bursitis after [flu] vaccination at an additional rate of 7.78 cases per [one] million vaccinations,” making the association “much more than a ‘coincidence’” according to Dr. Srikumaran. Id. (citing Pet. Ex. 25 at 1, 4, 6).

## **2. Althen Prongs Two and Three**

Dr. Srikumaran averred “[t]he logical sequence of cause and effect established from the medical theory [] suggests the needle injection of [the] vaccine antigen inadvertently near the bursa or rotator cuff tendon[,] led to a strong immune mediated inflammatory reaction, causing [Petitioner’s] shoulder pain.” Pet. Ex. 19 at 13; see also Pet. Ex. 36 at 4. The “medical records clearly support the vaccination was the trigger for developing the shoulder pain.” Pet. Ex. 19 at 10. He opined this occurred within 48 hours of vaccination, and that there is no alternative cause of Petitioner’s left shoulder pain. Id. at 7.

According to Dr. Srikumaran, Petitioner “consistently and reliably report[ed] immediate shoulder pain after vaccination to his varied medical providers.” Pet. Ex. 19 at 7. At the ED on September 12, 2013, three days after receiving the flu vaccine, “[Petitioner] state[d] that he had a

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<sup>23</sup> L.H. Martin Arias et al., Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder Following Vaccinations, 35 Vaccine 4870 (2017).

<sup>24</sup> Elisabeth M. Hesse et al., Risk for Subdeltoid Bursitis After Influenza Vaccination, 173 Annals Internal Med. 253 (2020).



flu shot a couple days ago; since then [he] had left sided chest pain, up into neck and down left arm; fe[lt] hard to breathe.” *Id.* (quoting Pet. Ex. 33 at 7). Cardiologist Dr. Block, who evaluated Petitioner the following day, wrote “there [was] no reason to even remotely suspect this is cardiac in nature,” and questioned whether Petitioner’s left arm pain was “related to reaction to recent intramuscular injection.” Pet. Ex. 36 at 1 (quoting Pet. Ex. 9 at 16). Similarly, when Petitioner presented to the ED on November 25, 2013, Petitioner reported “that his symptoms started after receiving the [flu] vaccine.” *Id.*; *see* Pet. Ex. 33 at 79. The diagnosis then was “left upper extremity muscular pain and cervical muscular pain.” Pet. Ex. 36 at 1; *see* Pet. Ex. 33 at 84. Petitioner continued to report the onset of his pain in relation to vaccination at later appointments. For example, in March 2014, orthopedist Dr. Esterberg noted “[Petitioner] did have a flu shot around the same time that it started and attribute[d] that to the ongoing pain.” Pet. Ex. 19 at 7 (quoting Pet. Ex. 32 at 129).

Dr. Srikumaran posited that when a patient’s recollections and reports regarding the initiation and causation of symptoms are “substantiated by physical exam[ination] findings[,] . . . a well-supported opinion as to causation” can be formulated. Pet. Ex. 36 at 3. Moreover, he found the proximate temporal relationship was consistently reported in Petitioner’s medical records. Pet. Ex. 19 at 13. This led Dr. Srikumaran to conclude Petitioner’s shoulder pain “beg[a]n immediately after the injection and worsened after [] time.” *Id.* at 8.

As stated previously, Dr. Srikumaran believed Petitioner did not have pain or dysfunction with his left shoulder or neck prior to the flu vaccine administered on September 9, 2013, and he distinguished Petitioner’s various ED visits involving chest pain above. *See* Pet. Ex. 19 at 13; Pet. Ex. 36 at 1-2. Regarding MRI and X-ray pathology showing consistencies with degenerative cervical spine disease, Dr. Srikumaran noted that most people Petitioner’s age “will have imaging findings of chronic degenerative conditions such as frayed or partially torn ligaments and tendons and arthritic joints (cervical-spine degeneration),” but like Petitioner, “the majority of these chronic conditions are asymptomatic.”<sup>25</sup> Pet. Ex. 19 at 11. What distinguishes Petitioner from these cases “is not whether there are chronic conditions present (we can all agree these chronic conditions are not caused by vaccinations), but rather what caused, or ‘triggered’, a previously asymptomatic chronic condition to become painful.” *Id.* So “[j]ust as we must contemplate the temporal relationship in regards to vaccination causing shoulder pain, we must do the same for the [P]etitioner’s neck pain and radiculopathy.” Pet. Ex. 36 at 3.

Consistent with Dr. Srikumaran’s theory, he stated it is the “inflammation directly related to vaccine antigen being delivered” that “initiates pain in previously long standing, silent, chronic degenerative conditions.” Pet. Ex. 19 at 11-12. And it is “logical to infer that the previously asymptomatic cervical spine pathology [] worsened, and became symptomatic,

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<sup>25</sup> Cervical spondylosis, for example “is a chronic, degenerative condition” and Dr. Srikumaran acknowledged “the sequelae of this condition can lead to radicular symptoms.” Pet. Ex. 36 at 3. Cervical spondylosis is a “degenerative joint disease affecting the cervical vertebrae, intervertebral disks, and surrounding ligaments and connective tissue, sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots.” Cervical Spondylosis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=107846> (last visited July 26, 2023).

following the vaccination which caused shoulder pain, and in turn caused compensatory neck pain.” Pet. Ex. 36 at 3-4. He “believe[d] the mechanism started with the vaccination into the shoulder, causing shoulder pain and dysfunction, resulting in compensatory muscle activity around the shoulder blade and neck, aggravating a previously asymptomatic chronic neck condition.” Pet. Ex. 19 at 12.

Supporting his position that neck and radiculopathy symptoms were triggered or worsened by the preceding shoulder injury, Dr. Srikumaran referenced the ED visit on September 12, 2013 (three days after the flu vaccination), where it was “reported that after receiving the vaccination, ‘[Petitioner’s] left arm swelled, and he [] had pain in the left arm constantly, with some radiation into the left side of the neck.’” Pet. Ex. 36 at 4 (quoting Pet. Ex. 9 at 15). He said this is consistent with Hawkins et al. and Manifold and McCann which “support the ability of shoulder pathology to affect neck symptoms.” Id. at 4 (citing Pet. Exs. 23, 27).

Thus, he did not dismiss that a cervical condition exists and indeed found evidence of both conditions, but he averred that the chronic neck condition was not the cause of Petitioner’s shoulder pain, and in fact, was the opposite. Pet. Ex. 19 at 10; Pet. Ex. 36 at 3. “The cervical radiculopathy and degeneration, . . . is a degenerative disorder, not caused by [Petitioner’s] vaccination, but very likely symptomatically exacerbated by the vaccination and subsequent shoulder pain.” Pet. Ex. 19 at 10. Regarding any other alternative causation theories, Dr. Srikumaran disagreed with Respondent’s experts. See Pet. Ex. 36 at 1-3.

Dr. Srikumaran disagreed with Dr. Abrams’ opinion that Petitioner meets the diagnostic criteria for fibromyalgia and could be the source of Petitioner’s shoulder pain. Pet. Ex. 36 at 2; Resp. Ex. A at 15. Dr. Srikumaran believed that using the widespread pain index (“WPI”) and symptom severity (“SS”) scale to diagnose fibromyalgia requires a “component of these symptoms occurring simultaneously.” Pet. Ex. 36 at 2. Thus, he took issue with Dr. Abrams’ calculation of the WPI and SS scale in which he used data from different points in time and across different visits to providers. Id. He posited one “cannot diagnose someone with fibromyalgia because they have pain in varying bodily areas over the course of a year and combine that with extrapolated answers from a separate mental health scale from [three] years prior to fit the appropriate scale that is typically used” in diagnosing fibromyalgia. Id. Moreover, consistent with his earlier position regarding the fourth criterion for a Table claim, Dr. Srikumaran added “the fact that the [P]etitioner does have chronic pain does not preclude him from qualifying for a SIRVA injury, especially because the type of pain described in the records is for low back pain with limited complaints to other body parts.” Id.; see also Pet. Ex. 19 at 10.

In contrast, Dr. Srikumaran agreed with Dr. Abrams regarding patients with diabetes and the propensity for shoulder pain. Pet. Ex. 36 at 2; Resp. Ex. A at 15. “However, given the temporal relationship in this case,” Dr. Srikumaran opined “it is more likely that [] [P]etitioner developed shoulder pain secondary to a vaccination, rather than spontaneously and randomly due to carrying a medical diagnosis.” Pet. Ex. 36 at 2-3. He explained that while there can be “many triggers to inflammation that cause shoulder pain to become symptomatic . . . in this case we do indeed have a trigger with a strong, reliably[,] and consistently reported, temporal association.” Id. at 3; see also Pet. Ex. 19 at 13.

## 2. Respondent's Expert, Dr. Geoffrey D. Abrams<sup>26</sup>

### a. Background and Qualifications

Dr. Abrams is a board-certified orthopedic surgeon with a subspecialty certification in sports medicine. Resp. Ex. A. at 1. He earned his M.D. at the University of California, San Diego and completed his residency in orthopedic surgery at Stanford University. Resp. Ex. B at 1. Dr. Abrams has a surgical practice focused on orthopedic conditions of the shoulder and serves as the Director of the Lacob Family Sports Medicine Center at Stanford University. Resp. Ex. A at 1. Dr. Abrams is also an Assistant Professor of Orthopedic Surgery at the Stanford University School of Medicine. Id. He has published numerous articles on shoulder and other musculoskeletal pathology. Id.; Resp. Ex. B at 2-8.

### b. Opinion

Dr. Abrams primarily raised Petitioner's other medical conditions as the cause or causes of his shoulder pain, opining Petitioner's "pre-existing medical comorbidities [are] much more likely to be the cause of his neck and upper extremity pain than the vaccine administration in September of 2013." Resp. Ex. A at 11, 15, 18. Accordingly, Dr. Abrams disputed that Petitioner meets the criteria for a SIRVA Table claim and further opined that his shoulder pain was "unlikely" caused-in-fact by the flu vaccine. Id. at 18.

Dr. Abrams first disagreed with Dr. Srikumaran on the Table SIRVA criteria, particularly disagreeing that Petitioner "did not have any medical history relating to the left upper extremity" prior to the September 9, 2013 flu vaccination. Resp. Ex. A at 11. He stated Petitioner had a "history of non-cardiac etiology left upper extremity pain prior to the vaccination in September of 2013 that matche[d] many of his presentations for left upper extremity pain following the vaccination in question." Id. at 11-12. Dr. Abrams noted this history includes ED presentations in November 2010, where he complained of "chest pain radiating to [the] left arm," and March 2011, where he complained of "pain and pressure in the chest that radiated to the left upper extremity." Id. (quoting Pet. Ex. 9 at 1, 58). He observed that while Petitioner does have a known history of cardiac disease, was found to have acute cardiac issues, and had a stent placement at the March 2011 visit, the November 2010 visit was negative for any cardiac issues. Id. at 12. Dr. Abrams indicated Petitioner had similar complaints with negative workup for acute cardiac issues following the September 2013 flu vaccination. Id. He also pointed out that on a 2016 intake form at the Swedish Hospital's Pain Clinic, Petitioner self-reported that the pain in his "neck," "arms," and "head" had been present since "11" when asked "date started." Id. (citing Pet. Ex. 34 at 39). Dr. Abrams interpreted this to mean "2011." Id. (citing Pet. Ex. 34 at 39).

Dr. Abrams conceded that Petitioner reported "neck and left upper extremity pain within a relatively short time-period following the September 2013 vaccination." Resp. Ex. A at 17. However, it was Dr. Abrams' opinion that the earlier events place the onset of symptoms prior to

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<sup>26</sup> Respondent submitted one expert report authored by Dr. Abrams. Resp. Ex. A.

vaccination and thus disqualify Petitioner's SIRVA Table claim for failure to meet the first criterion. Id. at 12.

Additionally, Dr. Abrams disagreed with Dr. Srikumaran that "shoulder pain radiating down the arm does not preclude a SIRVA diagnosis." Resp. Ex. A at 14. While he noted patients may develop shoulder specific pathology secondary to radiculopathy, Petitioner's clinical course did not point in this direction because he "specifically report[ed] radiation of pain down to the hands (on multiple occasions)." Id. Dr. Abrams opined this is not consistent with SIRVA and instead is consistent with Petitioner's "known radiographic cervical spine disease." Id. He referred to Petitioner's X-ray and MRI findings of "retrolisthesis of C4 on C5" and "moderate narrowing with endplate spurring changes at C4-5" as evidence. Id. at 13 (quoting Pet. Ex. 30 at 55). He added that "these findings take years to develop and were certainly present prior to the vaccination in question." Id.

Dr. Abrams argued Dr. Srikumaran's statement that the flu vaccination "triggered and exacerbated a pre-existing cervical degenerative condition" is unsupported in this case. Resp. Ex. A at 14 (quoting Pet. Ex. 19 at 10). He criticized the proposition that cervical radiculopathy could not explain shoulder symptoms but could explain neck pain and radiation beyond the shoulder. Id. He reasoned that the Gorski et al. study, relied on by Dr. Srikumaran, "included patients with pain in the superior-medial border of the scapula (not the neck itself), were of an average age of 33 years old, were 80% female, and . . . had no documented cervical spine pathology, no radicular symptoms, nor any stated diagnoses of chronic pain." Id. (internal quotations omitted). Therefore, Dr. Abrams opined it was "qualitatively different" due to Petitioner's age and clinical course. Id.

But relying on Dr. Srikumaran's expert report, Dr. Abrams discussed how Petitioner's symptoms do match those associated with cervical radiculopathy such as "[b]urning or electric pain, classically starting in the neck and radiating through the shoulder,"<sup>27</sup> "[w]eakness without pain," and "[n]eck and shoulder pain with loss of hand dexterity." Resp. Ex. A at 13-14 (quoting Pet. Ex. 19 at 9). Petitioner reported "radiating [pain] to left arm," and pain "extending from the left side of his neck, through the left shoulder, lateral arm, dorsal forearm, and into the dorsal hand in the mid aspect." Id. (quoting Pet. Ex. 32 at 129). Petitioner also reported dropping things, neck and shoulder pain, and loss of hand dexterity. Id. (citing Pet. Ex. 12 at ¶¶ 6-7). Cooper et al.,<sup>28</sup> which studied the frequency of patients with different locations of cervical disease and pain in various parts of the body, found that neck and shoulder pain was seen in many patients with cervical spondylosis. Id. at 14 (citing Resp. Ex. A, Tab 2 at 7-8).

Thus, Dr. Abrams proposed that cervical spine pathology and cervical spondylosis were likely the causes of Petitioner's neck and shoulder pain, rather than shoulder pathology as discussed by Dr. Srikumaran. Resp. Ex. A at 12, 14. In his experience, "having a single [] location of pathology to explain a patient's symptoms is more likely than trying to connect two

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<sup>27</sup> Petitioner's medical records do not evidence that he described his shoulder pain, radiating pain, or other symptoms as "burning or electric."

<sup>28</sup> Grant Cooper et al., Cervical Zygapophysial Joint Pain Maps, 8 Pain Med. 344 (2007).

disparate diagnoses—such as shoulder impingement causing neck pain (which is very uncommon) on top of an underlying cervical radiculopathy.” Id. at 14-15. Instead, Dr. Abrams opined “a single unifying diagnosis makes more sense in this case: [P]etitioner’s underlying cervical disease leading to his upper extremity symptoms.” Id.

Next, Dr. Abrams opined that Petitioner’s other medical conditions, such as diabetes, chronic pain, and likely fibromyalgia, also contributed to his upper extremity pain. Resp. Ex. A at 15. He opined Petitioner’s “pre-existing medical comorbidities [are] much more likely to be the cause of his neck and upper extremity pain than the vaccine administration in September of 2013.” Id. at 18.

Dr. Abrams first pointed out Petitioner’s well-documented diabetes diagnosis and that shoulder impairments in patients with diabetes is “extremely common.” Resp. Ex. A at 15. In Shah et al.,<sup>29</sup> for example, 63% of participants with diabetes mellitus had shoulder pain or disability. Resp. Ex. A, Tab 4 at 5. “Many of these shoulder impairments [were] the result of tendinopathy, or disease of the tendon, of which diabetes is a well-known risk factor.” Resp. Ex. A at 15 (citing Resp. Ex. A, Tabs 5-6).<sup>30</sup> Yamiguchi et al.<sup>31</sup> reported a high correlation between rotator cuff disease (partial or full thickness), even on their contralateral asymptomatic shoulder, and increasing age. Resp. Ex. A, Tab 7 at 1. Based on this literature, Dr. Abrams opined that while Petitioner did not have an MRI of the shoulder, “there is near certainty that in someone of [ ] [P]etitioner’s age and medical status, he has tendon disease within the shoulder.” Resp. Ex. A at 15.

Dr. Abrams then noted Petitioner’s “chronic pain” diagnosis as a source of his upper extremity pain. Resp. Ex. A at 15. Petitioner had nine PCP visits for chronic pain in the nine months prior to the September 2013 flu vaccination.<sup>32</sup> Id. at 12-13. At each of these visits, he was prescribed opioid pain medication to manage his chronic pain. Id. at 13. Although Dr. Abrams does not treat patients with chronic pain, he stated, based on his experience treating patients with shoulder pain who also have chronic pain, that it is common “to report long-standing pain in other locations that then spread[s] to the shoulder area.” Id.

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<sup>29</sup> K.M. Shah et al., Upper Extremity Impairments, Pain and Disability in Patients with Diabetes Mellitus, 2 *Physiotherapy* 147 (2015).

<sup>30</sup> Young Hak Roh et al., Effect of Metabolic Syndrome on the Functional Outcome of Corticosteroid Injection for Lateral Epicondylitis: Retrospective Matched Case-Control Study, 7 *Sci. Reps.* 10845 (2017); Michele Abate et al., Occurrence of Tendon Pathologies in Metabolic Disorders, 52 *Rheumatology* 599 (2013).

<sup>31</sup> Ken Yamaguchi et al., The Demographic and Morphological Features of Rotator Cuff Disease, 88 *J. Bone & Joint Surgery* 1699 (2006).

<sup>32</sup> The location of chronic pain at these visits was primarily Petitioner’s low back but generalized muscle pain was also noted. Pet. Ex. 32 at 54-64 (documenting “multiple chronic medical problems,” chronic low back and muscles,” “chronic pain,” “low back pain/myalgia/chronic pain,” and “pain low back atypical radiation to legs, muscle aches”).



Considering the various areas of chronic pain in Petitioner's body, Dr. Abrams questioned whether Petitioner may have fibromyalgia, which he highlighted is "a known cause of musculoskeletal (and shoulder) pain." Resp. Ex. A at 15. While he admitted he is not a pain specialist, he indicated he is familiar with the diagnostic criteria for fibromyalgia: (1) a WPI<sup>33</sup> and SS scale<sup>34</sup> within or greater than given criteria;<sup>35</sup> (2) symptoms that have been consistently present for at least three months; and (3) no other disorder that would otherwise explain the pain. Id. at 15-17 (citing Resp. Ex. A, Tab 9 at 8 tbl.4).

Dr. Abrams averred Petitioner meets all diagnostic criteria of fibromyalgia and did so prior to the September 2013 flu vaccination. Resp. Ex. A at 17. He concluded that because Petitioner reported "pain in whole body," Petitioner exceeds "seven sites of anatomic pain and therefore exceeds uppermost criteria for the WPI." Id. (quoting Pet. Ex. 11 at 79 (progress notes from a wellness visit on September 29, 2017)). Dr. Abrams stated Petitioner's WPI index combined with a December 2013 health questionnaire indicating Petitioner experienced "little interest or pleasure in doing things" as well as "moving and speaking slowly," fulfills the SS scale score criteria. Id. (quoting Pet. Ex. 32 at 118). He averred the doctor visits complaining of chronic pain have dated back several years, and "[w]hile [] [P]etitioner does have cervical spondylosis and radiculopathy, there are no other documented explanations for his back, leg, or gum pain." Id.

Finally, with regard to the timing of shoulder pain onset with relation to the vaccine administration and SIRVA criteria, Dr. Abrams stated, "just because symptoms are proximate to the vaccination, or in this case the re-appearance of pre-vaccination symptoms, we cannot assume a causal association." Resp. Ex. A at 17. Dr. Abrams did not otherwise refute Dr. Srikumaran's opinion that Petitioner had onset of shoulder pain within 48 hours of vaccination.

### **3. Respondent's Expert, Dr. Brian C. Callaghan<sup>36</sup>**

#### **a. Background and Qualifications**

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<sup>33</sup> WPI is based on the number of areas of pain and includes 19 possible locations: left and right shoulder girdle, left and right upper arm, left and right lower arm, left and right hip, left and right upper leg, left and right lower leg, left and right jaw, chest, abdomen, upper and lower back, and neck. Resp. Ex. A, Tab 9 at 8 tbl.4 (Fredrick Wolfe et al., The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity, 62 Arthritis Care & Rsch. 600 (2010)). One point is given for each possible location. Id.

<sup>34</sup> The SS scale score is the sum of the severity (0-3) of each somatic symptoms: fatigue, waking un-refreshed, and cognitive symptoms. Resp. Ex. A, Tab 9 at 8 tbl.4.

<sup>35</sup> WPI  $\geq 7$  and SS  $\geq 5$ , or WPI 3-6 and SS  $\geq 9$ . Resp. Ex. A at 15 (citing Resp. Ex. A, Tab 9 at 8).

<sup>36</sup> Respondent submitted one expert report authored by Dr. Callaghan. Resp. Ex. C.

Dr. Callaghan is a board-certified neuromuscular specialist. Resp. Ex. C at 1. He earned his M.D. from the University of Pennsylvania Medical Center and his M.S. in Clinical Research Design and Statistical Analysis at the University of Michigan. Resp. Ex. D at 1. He completed his residency in neurology and completed a neuromuscular fellowship. Id. Dr. Callaghan is a staff physician in the Department of Neurology for the Veterans Affairs Ann Arbor Health System. Id. at 2. As a neuromuscular specialist, his primary clinical interest is in neuropathy, and he has seen more than 200 patients with cervical radiculopathy. Resp. Ex. C at 1. Dr. Callaghan is also an Associate Professor of Neurology at the University of Michigan. Id. He serves as co-section editor for a neurology journal, peer reviews for several neurology journals, and has over 100 publications with a focus on neuropathy, including the appropriate diagnostic evaluation and treatment. Id.; Resp. Ex. D at 4, 10-17.

### **b. Opinion**

Dr. Callaghan opined that Petitioner does not meet three of the four criteria for a SIRVA Table claim. Resp. Ex. C at 7. He also asserted that “the cause of Petitioner’s symptoms is more likely than not [] cervical radiculopathy.” Id. Further, he opined Petitioner’s cervical radiculopathy “was most likely caused by neuroforaminal narrowing from degenerative changes, and there is no evidence a vaccine can cause, or does cause, cervical radiculopathy.” Id.

With regard to the first SIRVA Table criterion (no history of pain in the affected shoulder), Dr. Callaghan agreed with Dr. Abrams’ position and specifically noted that Petitioner had “almost identical symptoms of neck pain radiating into his left arm documented in 2010.” Resp. Ex. C at 5. For the third SIRVA Table criterion (pain limited to the shoulder), he opined Petitioner’s pain and reduced range of motion was not limited to the shoulder because he reported radiating pain down his left arm and hand as well as neck pain. Id. Lastly, Dr. Callaghan found Petitioner does not meet the fourth SIRVA Table criterion because the diagnosis of cervical radiculopathy by his PCP and orthopedic physician is evidence of another condition that would explain Petitioner’s symptoms. Id. Dr. Callaghan did not dispute the second Table criterion (onset of shoulder pain within 48 hours of vaccination). Id.

Dr. Callaghan took issue with Dr. Srikumaran’s opinion that “pain radiating down the arm is not inconsistent with SIRVA” primarily because he did not provide evidence of “SIRVA patients presenting with symptoms such as decreased strength in the same hand, pain in the same side of the neck, and pain, numbness, and tingling down the same arm such as [P]etitioner described.” Resp. Ex. C at 5. Instead, Dr. Callaghan opined Petitioner’s symptoms, such as left-sided neck pain and numbness and tingling radiating into the left arm, forearm, and hand, are “more consistent with a diagnosis of cervical radiculopathy rather than SIRVA.” Id. at 6-7.

Further, Dr. Callaghan noted there is no evidence of shoulder pathology despite Dr. Srikumaran’s statement that there is “clearly” evidence for both cervical and shoulder pathology. Resp. Ex. C at 6 (quoting Pet. Ex. 19 at 10). Dr. Callaghan cited Bokshan et al. and Manifold and McCann for the proposition that medical imaging is the best way to differentiate between cervical and shoulder pathology. Id. (citing Pet. Exs. 21, 27); see also Resp. Ex. C, Tab 1.<sup>37</sup>

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<sup>37</sup> Brian C. Callaghan et al., Distal Symmetric Polyneuropathy, 314 JAMA 2172 (2015).

Additionally, Hesse et al. found three levels of diagnostic certainty: a definite diagnosis of shoulder bursitis can be confirmed only by medical imaging; a probable diagnosis of shoulder bursitis can be made by a specialty provider; and a possible diagnosis of shoulder bursitis can be made by any other provider. Pet. Ex. 25 at 2. Petitioner had a cervical MRI but did not have a shoulder MRI. See Resp. Ex. C at 6. And according to Dr. Callaghan, not only was there no imaging to diagnose Petitioner with shoulder bursitis, but there were also no providers who diagnosed Petitioner with shoulder bursitis. Id.

While he agreed with Dr. Srikumaran that MRIs of the cervical spine can show pathology not related to symptoms, Dr. Callaghan further offered that it is less likely the case “when the changes are in the exact location that would be expected from the [patient’s] symptoms.” Resp. Ex. C at 6. Here, the MRI of Petitioner’s cervical spine showed degenerative changes at C4/5. Id. Dr. Callaghan opined those findings “would be expected to compress the C5 nerve root, which often leads to radiating pain from the neck into the shoulder and arm.” Id.

Finally, in contrast to Dr. Srikumaran, Dr. Callaghan noted that “cervical radiculopathy can lead to shoulder and arm pain, but shoulder pathology cannot lead to symptoms [] of cervical radiculopathy.” Resp. Ex. C at 6. He stated that while cervical radiculopathy can result from trauma or precipitators, it can also occur without a clear trigger. Id. He added that his review of literature returned no studies supporting Dr. Srikumaran’s claim of shoulder pathology leading to a cervical radiculopathy. Id.

### III. DISCUSSION

#### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321

(quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

“Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case.” Flores v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner’s evidence on a requisite element of the [P]etitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

## **B. Factual Issues**

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, “in general, warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that “medical records are accurate and complete as to all the patient’s physical conditions”); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum.

Servs., No. 03-1585V, 2005 WL 6117475, at \*19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy, 23 Cl. Ct. at 733 (1991))). Ultimately, a determination regarding a witness’ credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at \*3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at \*3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

### C. Lookback Provision

The statutory deadlines for filing petitions under the Vaccine Act are set forth at § 16. Under the Vaccine Act, a person “who has sustained a vaccine-related injury” must file a claim within 36 months of the onset of the symptoms of the injury. § 16(a)(2). This period can be extended under § 16(b) of the Vaccine Act, which provides that

[i]f at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may . . . file a petition for such compensation not later than 2 years after the effective date of the revision.

§ 16(b). That same provision states that no compensation can be awarded under this paragraph where “the vaccine-related injury occurred more than 8 years before the date of the revision of the table.”<sup>38</sup> Id.

Section 16(b) is triggered “only if (1) eligibility is new or (2) eligibility is ‘significantly increase[d].’” O’Connell v. Sec’y of Health & Hum. Servs., 63 Fed. Cl. 49, 60 n.9 (2004); see also Gorski v. Sec’y of Health & Hum. Servs., No. 97-156V, 1997 WL 739497, at \*5 (Fed. Cl. Spec. Mstr. Nov. 13, 1997). The first application, where eligibility is new, “has been held to apply when a new vaccine is added to the table thereby creating eligibility for Program compensation.” Simpson v. Sec’y of Health & Hum. Servs., No. 17-944V, 2019 WL 11815360, at \*4 (Fed. Cl. Spec. Mstr. Aug. 7, 2019). The second application, when eligibility is

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<sup>38</sup> The Vaccine Table was revised and effective on March 21, 2017, to include SIRVA as a Table injury following administration of the seasonal flu vaccine. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294, 6295 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date, 82 Fed. Reg. 11321, 11321 (Feb. 22, 2017).



“significantly increase[d],” “has been held to apply when a new vaccine injury is added to the Table.” Id.

The phrase “significantly increase the likelihood of obtaining compensation” is not defined in the Vaccine Act. § 16(b); see also § 33 (general provision of the Vaccine Act that defines certain words). Although nonbinding, special masters have provided various interpretations of the § 16(b) look-back provision. See, e.g., K.G. v. Sec’y of Health & Hum. Servs., No. 18-120V, 2018 WL 5795834, at \*12 (Fed. Cl. Spec. Mstr. Aug. 17, 2018); Muchnick v. Sec’y of Health & Hum. Servs., No. 97-89V, 1998 WL 1012801, at \*7 (Fed. Cl. Spec. Mstr. July 15, 1998); Gorski, 1997 WL 739497, at \*4-5.

The first Program case that discussed the look-back provision followed the March 10, 1995 Table revision which added “chronic arthritis” as a Table injury for the measles-mumps-rubella (“MMR”) vaccination. Gorski, 1997 WL 739497. In Gorski, the special master described the look-back provision as “confusing on its face,” and—admitting it was an unexplored issue in the program—provided an interpretation of the statute as it pertained to “chronic arthritis.” Id. at \*2-3. The special master found that because the Table revision only added a Table claim for a defined injury, the Petitioner was not now, for the first time, “eligible” to assert such a claim because Petitioner was already “eligible” to file a non-Table claim prior to the revision. Id. at \*5. The special master also found that while it could be argued that adding a Table claim might “add[] credence to the general theory” that the vaccine can cause that injury, the Table revision did not affect an allegation that the vaccine actually caused an injury, and thus did not “significantly increase [Petitioner’s] likelihood of obtaining compensation.” Id.

In contrast, in Simpson, the undersigned found that the addition of a Table Guillain-Barre Syndrome (“GBS”) injury significantly increased the Petitioner’s likelihood for compensation. 2019 WL 11815360, at \*6-7. Simpson involved a GBS claim which narrowly missed the onset required under the Table and the undersigned determined the lookback provision applied and thus, the petition was timely filed. Id. at \*7. In reaching this result, the undersigned stressed Congressional intent when forming the Vaccine Program and the lack of specific language in the lookback provision excluding causation-in-fact claims. Id. at \*5-6 (citing legislative history at H.R. Rep. No. 908, at 3 reprinted in 1986 U.S.C.C.A.N. 6287, 6344).

Section 16(b) “is not a jurisdictional life-preserver for all claimants; it allows a petitioner additional time to file only when the substantive law is changed in his favor.” O’Connell, 63 Fed. Cl. at 60 n.9 (citing Gorski, 1997 WL 739497, at \*4 (“[B]ecause the Vaccine Injury Table was in fact revised to include a new ‘Table Injury’ . . . the possibility is raised that [P]etitioner could benefit from the added filing period provided in [§]16(b).”); Snawder v. Cohen, 749 F. Supp. 1473, 1477 n.4 (W.D. Ky. 1990) (noting this provision may be triggered “if the Vaccine Injury Table is revised to make vaccine-related injuries which were not formerly compensable eligible for compensation”)).

#### **D. Causation**

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a

vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Petitioner claims he suffered a SIRVA Table injury and claims in the alternative, that his injury was caused-in-fact by a vaccination. To prove the latter, Petitioner must establish, by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in Petitioner’s favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in a petitioner’s favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec’y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

#### IV. ANALYSIS

##### A. Diagnosis

The parties dispute the nature of Petitioner’s shoulder injury, including diagnosis. Dr. Srikumaran opines Petitioner developed a SIRVA following his September 9, 2013 flu vaccine

that subsequently triggered a previously asymptomatic degenerative cervical disease. He explains that Petitioner had no pre-existing shoulder pathology prior to vaccination, that Petitioner developed pain in his shoulder and arm within 24 hours of vaccination, and that there is no alternative cause for Petitioner's symptoms. Dr. Srikumaran acknowledges Petitioner's degenerative cervical disease but opines there was no evidence of cervical pathology prior to the flu vaccine and subsequent shoulder injury.

Dr. Abrams and Dr. Callaghan opine Petitioner suffered from cervical radiculopathy and/or other conditions, not a SIRVA, and that those conditions were the cause of Petitioner's shoulder pain. Both Dr. Abrams and Dr. Callaghan argue that Petitioner's symptoms of pain radiating to his neck and down his arm are more consistent with a cervical radiculopathy. Dr. Callaghan notes there is no evidence of shoulder pathology because Petitioner did not receive a shoulder MRI and no provider diagnosed Petitioner with shoulder bursitis.

For the following reasons, the undersigned finds preponderant evidence that Petitioner suffered from shoulder pain following flu vaccination.<sup>39</sup> First, while Petitioner did not have a left shoulder MRI to confirm a diagnosis, he had positive shoulder impingement tests including Neer, Hawkins, and empty can.

Second, several of Petitioner's treating providers documented that Petitioner had shoulder pain. Dr. Block's ultimate impression was "[l]eft arm pain, noncardiac." Pet. Ex. 33 at 35. Similarly, Dr. Sullivan wrote that Petitioner had "an injection in his left arm for a flu shot 2-3 days ago which may be the etiology of his pain." *Id.* at 24. After finding that Petitioner was tender in the general shoulder region and had increased pain with range of motion of the left shoulder, Dr. Davis diagnosed Petitioner with "[l]eft upper extremity muscular pain." *Id.* at 84. Dr. Davis also diagnosed Petitioner with cervical muscular pain, however, this diagnosis does not negate the primary diagnosis of shoulder pain.

Additionally, "[b]ursae and tendon in shoulder region" was listed as an acute problem in Petitioner's record. Pet. Ex. 32 at 49. And a referral for physical therapy lists diagnoses of left shoulder pain and rotator cuff syndrome as well as "left shoulder tendonitis, rotator cuff pain, [and] neck pain." Pet. Ex. 30 at 16-19. Therefore, the undersigned is not persuaded by Dr. Callaghan's arguments that there is no evidence of shoulder pathology.

Here, the undersigned gives deference to the statements of Petitioner's treating physicians as they are "in the best position" to determine Petitioner's injury and the cause of such injury. See *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326; *Cucuras*, 993 F.2d at 1528 (noting contemporaneous medical records, "in general, warrant consideration as trustworthy evidence"). Therefore, the undersigned finds Petitioner has proven by preponderant evidence that he suffered from shoulder pain following his flu vaccination in September 2013.

## **B. Table Claim**

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<sup>39</sup> The undersigned notes that Respondent conceded Petitioner had shoulder pain in arguing that Petitioner's pain was "never localized to the injection site" and instead is just referred to as "left shoulder pain." Resp. Response at 9 (emphasis omitted).

## 1. Criterion One: Prior Condition

The first criterion for a SIRVA Table injury is that there can be “no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection.” 42 C.F.R. § 100.3(c)(10)(i). Based upon a review of the record as a whole, including the medical records, affidavits, and expert reports, the undersigned finds Petitioner did not experience issues with his left shoulder prior to vaccination that “would explain the alleged signs, symptoms, [and] examination findings . . . after vaccine injection.” Id.

Petitioner’s history of left upper extremity pain, as pointed out by Drs. Abrams and Callaghan, was two years prior to vaccination and there is no indication that this was an ongoing shoulder issue prior to vaccination. Dr. Srikumaran opines that while Petitioner presented to the ED on several occasions, the cause of the presenting complaints was “found to be different” each time. Pet. Ex. 36 at 1.

In November 2010, Petitioner presented to the ED complaining of “chest pain radiating to his left arm.” Pet. Ex. 9 at 1. Petitioner associated this event with a recent colonoscopy. At this visit he was hypertensive (blood pressure 151/96). Because of his prior cardiac history, he was admitted and evaluated. Cardiologist Dr. Choudhury’s impression was hypertension and “[a]typical chest pain” with “no clinical signs of coronary ischemia.” Id. at 63. There is no evidence that Petitioner had ongoing shoulder pain or pain with range of motion of the shoulder. He was not diagnosed with a musculoskeletal problem related to the chest pain that radiated to his left arm.

Similarly, in March 2011, Petitioner presented to the ED complaining of pain in his chest radiating to his left upper extremity with shortness of breath, “reminiscent of the pain related to his previous heart attack.” Pet. Ex. 9 at 58. Past medical history again indicated his prior cardiac history. On examination, Petitioner’s blood pressure was 207/122. An EKG showed marked ST elevations “suggestive of substantial inferior myocardial infarction.” Id. at 58-59. Cardiologist Dr. Martin was contacted, and Petitioner’s diagnosis was ST elevation/acute myocardial infarction. Thus, this presentation of radiating pain into Petitioner’s left upper extremity was in the context of a heart attack. There is no indication that Petitioner had shoulder pain with range or motion, and he was not diagnosed with a musculoskeletal problem.

Further, in neither of these prior instances was the chest pain radiating to his left neck and arm attributed to vaccination or trauma. And these instances were at least two years prior to the vaccination at issue and there is no evidence of an ongoing shoulder issue prior to vaccination.

Unlike the 2010 and 2011 presentations, Dr. Block concluded “[t]here [was] no reason to even remotely suspect that this [was] cardiac in nature” when Petitioner presented to the ED in September 2013. Pet. Ex. 33 at 28. And unlike the 2010 and 2011 presentations, Petitioner did not have elevated blood pressure in September 2013. Further, Dr. Esterberg later noted that Petitioner “ha[d] not had this type of problem before.” Pet. Ex. 32 at 129. For these reasons, the

undersigned finds Petitioner's 2010 and 2011 presentations different than his September and November 2013 presentations following vaccination.

Additionally, Petitioner had no documented history of cervical radiculitis pre-vaccination. As discussed more below, cervical radiculitis or cervical radiculopathy is not documented in the medical records until March 2014, six months after his flu vaccination.<sup>40</sup> See Pet. Ex. 32 at 104-06, 129-30.

Next, while Dr. Abrams points out Petitioner had nine PCP visits for chronic pain in the nine months leading up to the September 2013 flu vaccination, the undersigned finds this unpersuasive as none of the visits identified shoulder pain.

Accordingly, the undersigned finds Petitioner's prior left upper extremity pain to be too remote and unrelated to Petitioner's shoulder pain following his flu vaccination on September 9, 2013.

Further, undersigned finds Petitioner did not experience issues with his left shoulder prior to vaccination that "would explain the alleged signs, symptoms, [and] examination findings . . . after vaccine injection." 42 C.F.R. § 100.3(c)(10)(i). To the extent that Petitioner had chest pain that radiated into his left upper extremity prior to vaccination, that would not explain his signs, symptoms, and examination findings after vaccination. After vaccination, Petitioner had positive shoulder impingement testing. His records show that he was assessed with tendon and bursae problems of the shoulder. And his physical therapy records identify his diagnoses as rotator cuff syndrome, left shoulder tendonitis, and rotator cuff pain. All of this evidence in Petitioner's medical records establish that he had a new condition that was musculoskeletal after vaccination that was different in nature than any prior complaints, and that could not be explained by his prior presentations—where the pain occurred during a hypertensive or cardiac event. Therefore, Petitioner satisfies the first Table criterion.

## **2. Criterion Two: Pain Onset**

The specified timeframe on the Vaccine Injury Table for SIRVA is 48 hours post-vaccination. 42 C.F.R. § 100.3(c)(10)(ii). Dr. Srikumaran opines Petitioner's pain occurred within the specified timeframe because Petitioner "consistently and reliably report[ed] immediate shoulder pain after vaccination to his varied medical providers." Pet. Ex. 19 at 7. Specifically, he concluded it "began immediately after the injection and worsened after [] time." Id. at 8. The undersigned agrees and finds Petitioner's pain began within 48 hours of vaccination. Other than arguing Petitioner had pre-existing left upper extremity pain, Respondent's experts do not dispute this second criterion.

The earliest in time medical record regarding onset is Petitioner's visit to the ED on September 12, 2013, three days after vaccination. Those records document, "[Petitioner] state[d]

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<sup>40</sup> While Petitioner did complain of some neck pain after vaccination and a cervical X-ray showed degenerative changes, he did not receive a diagnosis of cervical pathology until months later.



that he had a flu shot a couple days ago; since then [he] had left sided chest pain, up into neck and down left arm.” Pet. Ex. 33 at 7. And importantly, Dr. Spies recorded September 9, 2013, the date of vaccination, as the date of onset of Petitioner’s pain. Additionally, Dr. Block noted during the cardiology evaluation on September 13, that Petitioner received the flu vaccine and “[s]ubsequently, the left arm swelled, and he ha[d] had pain in the left arm constantly, with some radiation into the left side of his neck and a little bit into his chest.” *Id.* at 27. The undersigned finds these records provide a detailed and reliable factual description of Petitioner’s injury and supports an onset within 48 hours.

Moreover, Petitioner continued to relate the onset of his pain back in time to the vaccination at later appointments. For example, on November 25, Petitioner reported “left upper extremity pain” that “started back in September after intramuscular injection.” Pet. Ex. 33 at 79. And orthopedist Dr. Esterberg noted Petitioner’s symptoms “started acutely” and caused “pain ever since” and noted, “[h]e did have a flu shot around the same time that it started and attribute[d] that to the ongoing pain.” Pet. Ex. 32 at 129.

Additionally, in his declaration, Petitioner averred that his September 9, 2013 flu “shot hurt so bad and the pain was immediate. [He] even jumped when the needle went in.” Pet. Ex. 12 at ¶ 2. He recalled it hurt so much that he had to take pain medication when he got home but that even then, “the pain didn’t go away.” *Id.* Mrs. Kennedy, who took Petitioner to the appointment to get his flu shot, also recalled the subsequent events in her declaration. She remembered Petitioner telling her “Dr. Chhokar must have given him an extra dose because his shoulder was really sore and was bothering him” after his appointment and his pain continued in the subsequent weeks. Pet. Ex. 13 at ¶¶ 2-3. The undersigned finds Dr. Srikumaran’s opinions on the importance of a patient’s recollections regarding initiation of symptoms persuasive, especially when they are substantiated by medical records.

Based on the contemporaneous medical records, declarations, and expert reports, the undersigned finds the onset of Petitioner’s shoulder pain began on September 9, 2013, immediately after vaccination, and well within two days or 48 hours of his September 2013 vaccination, satisfying the second criterion. *See, e.g., Williams v. Sec’y of Health & Hum. Servs.*, No. 17-1046V, 2020 WL 3579763, at \*5 (Fed. Cl. Spec. Mstr. Apr. 1, 2020) (finding Petitioner’s onset of shoulder pain started within 48 hours of vaccination because the medical records consistently referred to onset “after” vaccination, “following” vaccination, “since” vaccination, and “very soon after” vaccination); *Humbert v. Sec’y of Health & Hum. Servs.*, No. 17-360V, 2023 WL 2565729, at \*25 (Fed. Cl. Spec. Mstr. Mar. 20, 2023) (using affidavit testimony in addition to medical records and expert reports to find onset began within two days of vaccination).

### **3. Criterion Three: Scope of Pain and Limited Range of Motion**

The third criterion requires Petitioner’s pain and reduced range of motion to be limited to the shoulder. 42 C.F.R. § 100.3(c)(10)(iii). This criterion “is intended to ensure that SIRVA claims are limited to instances in which “the condition is localized to the shoulder in which the vaccine was administered.” *Durham v. Sec’y of Health & Hum. Servs.*, No. 17-1899V, 2023 WL 3196229, at \*12 (Fed. Cl. Spec. Mstr. May 2, 2023) (quoting 82 Fed. Reg. 6294, 6296 (Jan.

19, 2017)). “[T]he gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder.” Id. (citing Grossman v. Sec’y of Health & Human Servs., No. 18-13V, 2022 WL 779666, at \*15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022)).

However, the third Table criterion “does not prevent a petitioner with simultaneous areas of pain from also meeting the Table SIRVA definition.” Rodgers v. Sec’y of Health & Hum. Servs., No. 18-0559V, 2021 WL 4772097, at \*8-9 (Fed. Cl. Spec. Mstr. Sept. 9, 2021); see also Werning v. Sec’y of Health & Hum. Servs., No. 18-0267V, 2020 WL 5051154, at \*10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that Petitioner satisfied the third SIRVA criterion where there was a complaint of radiating pain, but the Petitioner was “diagnosed and treated solely for pain and limited range of motion to her right shoulder”); Cross v. Sec’y of Health & Hum. Servs., No. 19-1958V, 2023 WL 120783, at \*7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023) (finding that “despite the notations of pain extending beyond the shoulder, Petitioner’s injury [was] consistent with the definition of SIRVA and there [was] not preponderant evidence of another etiology”); K.P. v. Sec’y of Health & Hum. Servs., No. 19-65V, 2022 WL 3226776, at \*8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that “claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body”).

Medical records document that Petitioner voiced subjective complaints of pain in his left arm and shoulder, as well as his left neck, and down his left arm following vaccination. See, e.g., Pet. Ex. 33 at 16 (noting “left sided chest pain which radiate[d] to left neck and down left arm”), 20 (documenting “pain in [] left side of his chest with radiation to his neck and arm”), 76 (describing “left sided neck pain that radiate[d] down [his] left shoulder to [his] arm and left chest”); Pet. Ex. 32 at 46 (documenting “neck pain radiating to left arm”), 129 (documenting “severe left upper extremity pain, numbness and paresthesias . . .” and that pain extended “from the left side of his neck, through the left shoulder, lateral arm, dorsal forearm, and into the dorsal hand”); Pet. Ex. 30 at 4 (describing “radicular type [symptoms] through the [left] [upper extremity]”). Dr. Block noted that Petitioner’s “left arm swelled” subsequently from the flu vaccination “and he ha[d] had pain in the left arm constantly, with some radiation into the left side of his neck and a little bit into his chest.” Pet. Ex. 33 at 27. And while “[t]here ha[d] been fixation on chest discomfort,” Petitioner’s “pain and discomfort [were] mainly in his arm.” Id.

In addition to Petitioner’s presenting complaints of pain, physical examinations document Petitioner’s range of motion. Some medical records specifically address range of motion in the affected shoulder. For example, in October, Petitioner marked on a physical therapy patient worksheet that he could not “carry heavy loads overhead” or “reach up to a lower shelf without increased symptoms.” Pet. Ex. 30 at 65. And at the November 25, 2013 ED visit, Petitioner’s “[p]ain increase[d] with range of motion of left shoulder.” Pet. Ex. 33 at 81. Importantly, there was no associated numbness or weakness at that time. Id. at 79. A January 2014 physical therapy shoulder evaluation reflects Petitioner had difficulty lifting with his left arm, dressing himself, and performing general activities of daily living. Pet. Ex. 30 at 50.

But the records also indicate pain and decreased range of motion elsewhere. At the November 2013 ED visit, Petitioner was “[t]ender in the left lateral neck and general shoulder region.” Pet. Ex. 33 at 81-82 (emphasis added). In January 2014, his PCP Dr. Chhokar noted that Petitioner had “muscle tenderness, mild dec[reased] [range of motion] left shoulder, neck.” Pet. Ex. 32 at 49. Physical examination with orthopedist Dr. Esterberg in March 2014 revealed “[n]ormal neck alignment, although he [held] in a slightly flexed position . . . increased pain with extension of his neck,” but “full extension range of motion.” Id. at 130. He also had slightly diminished sensation over the dorsal left hand. Id.

The first time a non-cardiac diagnosis was made for Petitioner’s left upper extremity pain was when he presented to the ED in November 2013, approximately two months after the flu vaccination. Petitioner reported that “[t]he pain started back in September after intramuscular injection.” Pet. Ex. 33 at 79. Petitioner was tender in the neck and shoulder region and his pain increased with range of motion of his shoulder. Importantly, there was no associated numbness or weakness. Dr. Davis’ impression included “[l]eft upper extremity muscular pain.” Id. at 84. As discussed in the diagnosis section above, while cervical muscular pain was also in the diagnosis, it does not negate the diagnosis of shoulder pain.

Cervicalgia was listed as an acute problem on December 6, 2013, although it appears this is because Petitioner indicated to his PCP that he was seen in the ED two weeks prior for “muscle strain neck and right shoulder,” with “no acute radicular [symptoms].” Pet. Ex. 32 at 50. Likewise, and shortly thereafter, Dr. Rains noted that Petitioner had “L[eft] neck, shoulder, and upper arm pain since [flu] shot L[eft] shoulder [November 2013], seen in [ED] November 25, 2013 and [diagnosed] w[ith] cervical strain and [left] shoulder sprain.” Id. at 125, 127.

Complaints of shoulder pain continued and were entertained by treating physicians. “Bursae and tendon in shoulder region” was listed as an acute problem by Dr. Chhokar in January 2014. Pet. Ex. 32 at 49. A left shoulder X-ray was ordered and showed the shoulder was within normal limits and a cervical spine X-ray showed degenerative disc disease. But Petitioner was only referred to physical therapy for his shoulder at that time. The referral for physical therapy from January 2014 lists diagnoses of left shoulder pain and rotator cuff syndrome as well as “left shoulder tendonitis, rotator cuff pain, [and] neck pain.” Id. at 16-19. No cervical issue was noted. Id.

Petitioner’s expert, Dr. Srikumaran, provides several explanations for the presence of neck pain in the context of a SIRVA injury. First, he describes the overlapping characteristics of shoulder pathology with cervical pathology and states that radiation of pain, for example, “is simply one way to characterize the pain and is common in various directions for common shoulder related diagnoses such as bursitis or capsulitis.” Pet. Ex. 19 at 8. “The proposed mechanism explaining this connection is muscular spasm or dysfunction of the numerous muscles that connect the shoulder and neck.” Pet. Ex. 19 at 9 (citing Pet. Ex. 17 at 3). Bokshan et al. found that “pain in the neck may represent referred pain from the shoulder girdle and vice versa.” Pet. Ex. 21 at 1. Because there are layers of muscles, ligaments, and tendons that bridge the areas among the shoulder region and cervical spine, Dr. Srikumaran opines “it is easy to understand that an injury affecting one area of the shoulder . . . can cause compensatory overuse of surrounding musculature, particularly [] leading into the neck.” Pet. Ex. 36 at 4.

Second, and discussed more below, Dr. Srikumaran opines that the pre-existing cervical radiculopathy “is a degenerative disorder, not caused by his vaccination, but very likely symptomatically exacerbated by the vaccination and subsequent shoulder pain” but that those symptoms are separate from the shoulder pathology. Pet. Ex. 19 at 10. In sum, Petitioner argues, “It was not that the vaccine caused a direct injury to the shoulder and the neck. Without the shoulder [injury], the SIRVA, there would be no neck pain as pain would not have radiated from the primary source of injury (shoulder) to the neck or beyond.” Pet. Mot. at 10.

Respondent’s experts disagree and argue pain radiating to Petitioner’s neck and arm is inconsistent with a SIRVA Table claim. Dr. Abrams asserts that Petitioner’s clinical course was due to radiculopathy because he “specifically report[ed] radiation of pain down to the hands (on multiple occasions).” Resp. Ex. A at 14. Dr. Abrams opines radiation of pain is more consistent with Petitioner’s “known radiographic cervical spine disease.” Id. However, Dr. Abrams admitted that the MRI findings of degenerative cervical spine disease “take years to develop and were certainly present prior to the vaccination in question.” Resp. Ex. A at 13. But as discussed throughout, the cervical spine disease was not discovered until after Petitioner’s presentation of shoulder complaints.

Dr. Callaghan opines Petitioner’s symptoms of left-sided neck pain, numbness and tingling radiating into the left arm, forearm, and hand are “more consistent with a diagnosis of cervical radiculopathy rather than SIRVA.” Resp. Ex. C at 6-7. He points out that Dr. Srikumaran did not provide evidence of “SIRVA patients presenting with symptoms such as decreased strength in the same hand, pain in the same side of the neck, and pain, numbness, and tingling down the same arm such as [P]etitioner described.” Id. at 5.

In sum, Petitioner had pain radiating to his arms, hand, and neck and therefore his pain was not limited to his shoulder and does not meet the third Table criterion.

#### **4. Criterion Four: Other Condition or Abnormality**

The fourth criterion requires that “[n]o other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).” 42 C.F.R. § 100.3(c)(10)(iv). Under this specific language and the facts of this case, Petitioner bears the burden of “establishing that any clinical evidence of cervical radiculopathy that is present is not meaningful to the existence of [his] symptoms.” Durham, 2023 WL 3196229, at \*14. That, is, he must “prove by preponderant evidence either (a) that [his] history is entirely free of, for example, clinical evidence of radiculopathy, or (b) if not, that the radiculopathy would not explain [his] symptoms.” Id.

Because a cervical MRI revealed degenerative changes at C3-4 and C4-5, the fourth SIRVA Table criterion turns on whether the cervical radiculopathy explains Petitioner’s shoulder symptoms. Petitioner argues cervical radiculopathy cannot explain all of Petitioner’s symptoms. Specifically, that his previously asymptomatic radiculopathy cannot explain his “dramatic” onset of shoulder symptoms. Pet. Mot. at 10-11. Respondent disagrees and argues that Petitioner’s

shoulder pain can be explained by his cervical radiculopathy (and other medical conditions) rather than by the flu vaccine. See Resp. Response at 14, 19.

Throughout Petitioner's clinical presentation, both shoulder and neck (cervical spine) issues were addressed. Petitioner's shoulder pain was frequently documented, he received a left shoulder X-ray, and was referred to physical therapy for his left shoulder. The symptoms extending beyond Petitioner's shoulder were recognized by Petitioner's providers and he subsequently received cervical imaging.

In February 2014, Dr. Chhokar listed "[b]rachial neuritis or radiculitis" and "degeneration of cervical intervertebral disc" as acute problems. Pet. Ex. 32 at 47. A diagnosis of brachial neuritis was not further entertained. It was not until March 2014, approximately six months after the flu vaccination, that Petitioner received a cervical diagnosis. It was a PCP referral to an orthopedist documenting Petitioner's diagnosis as "cervical spine degenerative disc disease C4-5[,] C5 cervical radiculitis, [and] left arm/shoulder pain." Id. at 104. Dr. Esterberg's impression later that month was "cervical radiculitis, cervical radiculopathy, [ ] left side, likely C7." Id. at 130. But it was not until June 2014 that Petitioner underwent a cervical MRI which confirmed degenerative changes at C3-4 and C4-5. Id. at 133. Upon review of that MRI, Dr. Esterberg opined Petitioner had "C4-5 stenosis which may be causing a cervical radiculitis, but the distribution is throughout the left upper extremity." Id. He noted it was "nondermatomal." Id.

But despite both conditions being entertained by providers for the months following vaccination, the undersigned notes that several providers attributed Petitioner's shoulder pain to the flu vaccine, not to the degenerative cervical disease. For example, Dr. Block documented that Petitioner's "left arm swelled" subsequently from the flu vaccination. Pet. Ex. 33 at 27. His impression was "[l]eft arm pain" and questioned whether it was "related to reaction to recent intramuscular injection." Id. at 28. And the following day, Dr. Sullivan wrote that Petitioner had "an injection in his left arm for a flu shot 2-3 days ago which may be the etiology of his pain." Pet. Ex. 33 at 24.

Other records also associate Petitioner's pain to the flu vaccine. Nursing notes from September 12, 2013 report Petitioner had pain "since having a flu shot on 9/[9], [Petitioner] report[ed] at first he thought this pain was due to the flu shot." Pet. Ex. 33 at 9. ED notes from November 25 report Petitioner's "left upper extremity pain" "started back in September after intramuscular injection." Id. at 79. And orthopedist Dr. Esterberg noted Petitioner's symptoms "started acutely" and caused "pain ever since" and noted, "[h]e did have a flu shot around the same time that it started and attribute[d] that to the ongoing pain." Pet. Ex. 32 at 129. And Dr. Esterberg appeared to question whether the cervical radiculitis was causing all of Petitioner's symptoms, but then rejected that idea because the location of the pain was in the shoulder. See id. at 133 (opining Petitioner had "C4-5 stenosis which may be causing a cervical radiculitis, but the distribution is throughout the left upper extremity").

"[T]he opinions of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at \*8 (Fed. Cl. Spec. Mstr. July 2, 2019). An opinion by a treating physician that is not



supported by a factual basis or other evidence is conclusory in nature. And a “treating physician’s recognition of a temporal relationship does not advance the analysis of causation.” Isaac v. Sec’y of Health & Hum. Servs., No. 08-601V, 2012 WL 3609993, at \*26 (Fed. Cl. Spec. Mstr. July 30, 2012); see also Robertson v. Sec’y of Health & Hum. Servs., No. 18-554V, 2022 WL 17484980, at \*17 (Fed. Cl. Spec. Mstr. Dec. 7, 2022) (finding treating physicians’ statements of mere suspicion fall short of an opinion supporting vaccine causation); Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1347 (Fed. Cir. 2010) (concluding the special master did not err in affording little weight to the opinions of Petitioner’s treating physicians where “none of the treating physicians concluded that the [] vaccine caused [Petitioner’s] [condition]”).

Here, there are a number of references to the flu vaccine by Petitioner’s treating healthcare providers. While none of them directly state that the flu vaccine caused the left upper extremity pain, they show that the providers questioned causation. Further, Dr. Esterberg contemplated whether Petitioner’s cervical stenosis was causing his shoulder pain but rejected that idea due to the distribution of the pain. Dr. Esterberg’s note is important because it corroborates Dr. Srikumaran’s opinion that the cervical pathology was not the cause of Petitioner’s shoulder pain.

Moreover, Dr. Srikumaran opines that the vaccination triggered Petitioner’s cervical problems. He states “the vaccination triggered and exacerbated a pre-existing [but asymptomatic] cervical degenerative condition.” Pet. Ex. 19 at 10. “[T]he time course suggests [Petitioner] started to experience shoulder and arm pain first, and this later led to cervical pain, neither of which he had any evidence of prior to vaccination.” Id.; see also Pet. Ex. 36 at 3. This is consistent with the medical records as there is no documented history of cervical radiculopathy prior to Petitioner’s September 2013 flu vaccination. Moreover, Dr. Callaghan admits cervical radiculopathy can be triggered from trauma. See Resp. Ex. C at 6.

Atanasoff et al. states that in many cases, conditions including “impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis[,] and adhesive capsulitis[,] . . . may cause no symptoms until provoked by trauma or other events.” Pet. Ex. 14 at 3. The authors concluded that “some of the MRI findings . . . may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.” Id.

To help distinguish whether Petitioner’s shoulder symptoms can be explained by SIRVA or cervical radiculopathy, Dr. Srikumaran describes the clinical presentations of both conditions and compared them to Petitioner’s clinical course. Shoulder pathology includes “pain with arm/shoulder abduction (moving away from body and up, similar to impingement signs).” Pet. Ex. 19 at 8. Petitioner had limited range of motion in his left shoulder as well as pain with range of motion in his left shoulder. Petitioner also tested positive for impingement tests.

Manifold and McCann states that patients with primary shoulder disease have point tenderness over the shoulder, unlike patients with primary cervical spine disease. Pet. Ex. 27 at 3. Petitioner had tenderness in the shoulder region. See, e.g., Pet. Ex. 33 at 81-82; see also Pet. Ex. 32 at 49 (noting “muscle tenderness” in an unspecified location).

In a similar SIRVA case—albeit a causation-in-fact claim—Respondent’s experts opined Petitioner’s symptoms could be explained by cervical radiculopathy. Humbert, 2023 WL 2565729, at \*15, \*25. The undersigned found that opinion ignored the fact that Petitioner’s physicians gave him two distinct diagnoses. Id. at \*25. The Petitioner in Humbert was not initially diagnosed with cervical radiculopathy until after the vaccination. Id. Petitioner’s expert opined “it is common to have overlapping radicular and shoulder pathology but the presence of radicular pain [does] not . . . mean that the vaccine [did] not cause[] [Petitioner’s] shoulder injury.” Id. (internal quotations omitted); see also Gurney v. Sec’y Health & Hum. Servs., No. 17-481V, 2019 WL 2298790, at \*6 n.12 (Fed. Cl. Spec. Mstr. Mar. 19, 2019).

Likewise, in another causation-in-fact SIRVA case, Petitioner had hand numbness in addition to shoulder pain. Wolford v. Sec’y of Health & Hum. Servs., No. 17-451V, 2021 WL 3357987, at \*14 (Fed. Cl. Spec. Mstr. July 9, 2021). Respondent’s expert opined that Petitioner’s symptoms could be explained by his long standing and well-documented history of joint and back pain, and that his diagnosis of peripheral neuropathy explained Petitioner’s hand numbness. Id. Respondent’s experts also believed there were medical records documenting a longstanding history of cervical pain that would explain Petitioner’s symptoms. Id. Petitioner’s expert opined Petitioner’s injury was not neurologic and to the extent neurologic symptoms existed, they developed after the shoulder was injured by the vaccine. Id. at \*14.

In Wolford, the undersigned acknowledged Petitioner had history of back and joint pain as well as diabetic neuropathy. 2021 WL 3357987, at \*14. However, she found medical records did not support a longstanding history of cervical pain. Id. Relying on Atanasoff et al., the undersigned concluded that while Petitioner may have had pre-existing pathology, “he was not symptomatic until after vaccination.” Id. at \*15; see Pet. Ex. 14 at 3 (concluding that “some of the MRI findings . . . may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation”).

Such is the case here. The cervical pathology does not explain Petitioner’s shoulder symptoms, especially given that Petitioner had an abrupt onset of pain immediately after vaccination. Although Petitioner had cervical radiculopathy, that does not explain his shoulder pain, impingement testing, pain on range of motion of the shoulder, diagnosis of tendon and bursae problems, and the physical therapy referral diagnoses of left shoulder pain and rotator cuff syndrome, all of which are explained by his SIRVA. Thus, the undersigned finds that Petitioner meets the fourth SIRVA criterion.

In conclusion, while the undersigned finds Petitioner satisfies the first, second, and fourth Table criteria, she finds Petitioner does not satisfy the third Table criterion. Because a petitioner is only considered to have suffered a SIRVA Table injury if all of the criteria are met, Petitioner’s Table claim must fail. See 42 C.F.R § 100.3(c)(10).

### **C. Lookback Provision**

The lookback provision saves the non-Table version of Petitioner’s claim as timely. Under the Vaccine Act, a person “who has sustained a vaccine-related injury” must file a claim within 36 months of the onset of the symptoms of the injury. § 16(a)(2). This period can be

extended under § 16(b), which provides that “any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation,” such person may “file a petition for such compensation not later than [two] years after the effective date of the revision” provided the vaccine-related injury occurred within eight years before the date of the revision of the Table.

Petitioner argues his non-Table claim is timely under the lookback provision of § 16(b) of the Vaccine Act because the likelihood of success was significantly increased by the amendment adding SIRVA to the Vaccine Injury Table. Pet. Mot. at 16-17. Respondent argues that because Petitioner did not suffer a Table SIRVA, the lookback provision does not apply. Resp. Response at 11. Additionally, Respondent argues the lookback provision does not apply because Petitioner was eligible to seek compensation prior to the Table change, and thus the change did not significantly increase his likelihood of receiving compensation based on the facts and circumstances of this case. Resp. Response at 14-15.

Some Program cases have found the lookback provision does not apply when a case does not meet the stringent Table criteria. See, e.g., Duggirala v. Sec’y of Health & Hum. Servs., No. 18-1578V, 2021 WL 2878349, at \*1 (Fed. Cl. Spec. Mstr. June 7, 2021); Christensen v. Sec’y of Health & Hum. Servs., No. 18-1477V, 2021 WL 2419720, at \*6-7 (Fed. Cl. Spec. Mstr. May 12, 2021); Clavio v. Sec’y of Health & Hum. Servs., No. 17-1179V, 2022 WL 1078175, at \*5-7 (Fed. Cl. Spec. Mstr. Feb. 16, 2022).

But in Simpson, the undersigned found the lookback provision applied to Petitioner’s non-Table GBS claim because the revision “significantly increase[d] [P]etitioner’s claim.” 2019 WL 11815360, at \*6-7. In reaching this result, the undersigned stressed Congressional intent when forming the Vaccine Program and the lack of specific language in the lookback provision excluding causation-in-fact claims. Id. at \*5-6. The undersigned also relied on the volume of causation-in-fact GBS cases compensated in the Vaccine Program following the March 2017 Table revision adding GBS to the Table, and the fact that Petitioner’s injury was consistent with GBS, with a 47-day onset, five days outside the Table definition. Id.<sup>41</sup>

The undersigned maintains the same interpretation as applied in Simpson and interprets the lookback provision not in isolation, but in a broader context. The first group of claimants covered by § 16(b), those who were previously “not . . . eligible to seek compensation,” is narrowly, precisely defined. Congress could have used similarly definite language to restrict the second group of claimants, those whose likelihood of compensation was “significantly increase[d],” but declined to do so. No language in § 16(b) excludes causation-in-fact claims. In fact, no part of § 16 differentiates between Table injuries and causation-in-fact injuries, further

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<sup>41</sup> In another GBS case following the March 2017 Table revision, the special master determined that the lookback provision did not apply. K.G., 2018 WL 5795834, at \*12. The special master found Petitioner’s four-month onset of GBS post-vaccination was “wholly inconsistent with GBS” because the onset period was “too long outside the 42-day window to successfully establish a Table injury.” Id.

suggesting that Congress did not intend statute of limitations issues to turn on this distinction. Likewise, the undersigned does not find it reasonable to read such a restriction into the statute.

Additionally, there are several instances where a petitioner failed to meet the stringent criteria of a Table claim but prevailed as to a causation-in-fact claim. See, e.g., Layne v. Sec’y of Health & Hum. Servs., No. 18-57V, 2022 WL 3225437, at \*17-23 (Fed. Cl. Spec. Mstr. July 12, 2022); Colbert v. Sec’y of Health & Hum. Servs., No. 18-166V, 2022 WL 2232210, at \*17-23 (Fed. Cl. Spec. Mstr. May 27, 2022).

Here, Petitioner clearly established that he has a SIRVA although he fails to satisfy all of the Table criteria. The undersigned finds that because Petitioner narrowly missed the Table criteria, and due to the lack of specific language in the lookback provision excluding causation-in-fact claims, the lookback provision applies to Petitioner’s causation-in-fact-claim.

The Table was revised and became effective to include SIRVA as an injury following administration of the seasonal flu vaccine on March 21, 2017. 42 C.F.R. § 100.3(a)(XIV)(B). For the lookback provision to apply, Petitioner had until March 21, 2019, two years after the effective date of the revision, to file his petition. Additionally, Petitioner’s vaccine-related injury must have occurred within eight years before the date of the revision, or by March 21, 2009.

Petitioner filed his petition on February 13, 2018, well within the lookback provision time frame. Petitioner received the flu vaccine at issue on September 9, 2013, and initial manifestation of onset occurred on September 9, 2013. The undersigned finds Petitioner filed his petition within two years of the effective date of the revision for a vaccine-related injury that occurred within eight years before the date of the revision of the Table. Thus, under § 16(b), Petitioner’s petition was timely filed.

#### **D. Causation-in-Fact Analysis**

Because the undersigned finds the lookback provision applies, the undersigned must next analyze Petitioner’s causation-in-fact claim, specifically whether Petitioner has provided preponderant evidence of all three Althen prongs. For the following reasons, the undersigned finds Petitioner provided preponderant evidence that the flu vaccine caused his injury by satisfying all three Althen prongs.

##### **1. Althen Prong One**

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner’s theory of causation need not be medically or scientifically certain, but it must be informed by a “sound and reliable” medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec’y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”), aff’d, 475 F. App’x 765 (Fed. Cir. 2012). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination

of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The mechanism for a shoulder injury is well described by Dr. Srikumaran and the medical literature filed in this case. In Atanasoff et al., the authors propose that the causal mechanism “is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction.” Pet. Ex. 14 at 1. They found “rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response.” Id. at 3. MRI findings supported the conclusion that shoulder impairments, such as rotator cuff tears, “may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.” Id. Similarly, Bodor and Montalvo proposed that a “vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response.” Pet. Ex. 16 at 1-2. They found multiple structures within the shoulder involved, which suggested “a primary inflammatory etiology rather than a mechanical overuse problem.” Id. at 3.

Further, when proposing the addition of SIRVA to the Vaccine Table, Respondent discussed the mechanism by which this injury is caused. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015).

For the above reasons, the undersigned finds Petitioner has provided by preponderant evidence a sound and reliable theory that the flu vaccine administered intramuscularly can cause a shoulder injury, and therefore, Petitioner has satisfied the first Althen prong.

## 2. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general



acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is a preponderance of evidence in the record to support a logical sequence of cause and effect showing the September 9, 2013 flu vaccination caused Petitioner’s left shoulder pain. See Althen, 418 F.3d at 1278. The undersigned finds the evidence discussed earlier in this Ruling qualifies as preponderant evidence consistent with the mechanism to show a logical sequence of cause and effect that the flu vaccine caused Petitioner’s shoulder injury. See supra Section IV.B. This includes contemporaneous medical records documenting statements from treating providers, declarations, and the expert reports.

### 3. Althen Prong Three

Althen prong three requires Petitioner to establish a “proximate temporal relationship” between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a “medically acceptable temporal relationship.” Id. Petitioner must offer “preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn v. Sec’y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that “a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury”).

As stated above, the undersigned finds the onset of Petitioner’s left shoulder pain occurred on September 9, 2013, within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. See Althen, 418 F.3d at 1278.

The undersigned finds the evidence discussed in this Ruling qualifies as preponderant evidence to show the flu vaccine caused Petitioner’s shoulder injury within the time frame required. The temporal association is appropriate given the mechanism of injury. Thus, Petitioner has satisfied the third Althen prong.

### E. **Alternative Causation**

Because the undersigned concludes that Petitioner has established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence “that [Petitioner’s] injury was in fact caused by factors unrelated to the vaccine.” Whitecotton v. Sec’y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev’d on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec’y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to the

fourth Table criterion, the undersigned found Respondent failed to establish evidence to show that Petitioner's shoulder injury was caused by a source other than his vaccination. Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

## **V. CONCLUSION**

For the reasons discussed above, the undersigned finds that (1) Petitioner did not satisfy the SIRVA Table criteria, but (2) that the lookback provision of § 16(b) of the Vaccine Act applies, and thus, Petitioner's petition was timely filed, and (3) Petitioner has established by preponderant evidence that his flu vaccine caused his shoulder injury. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**

Nora Beth Dorsey  
Special Master